

**FIG. 1**

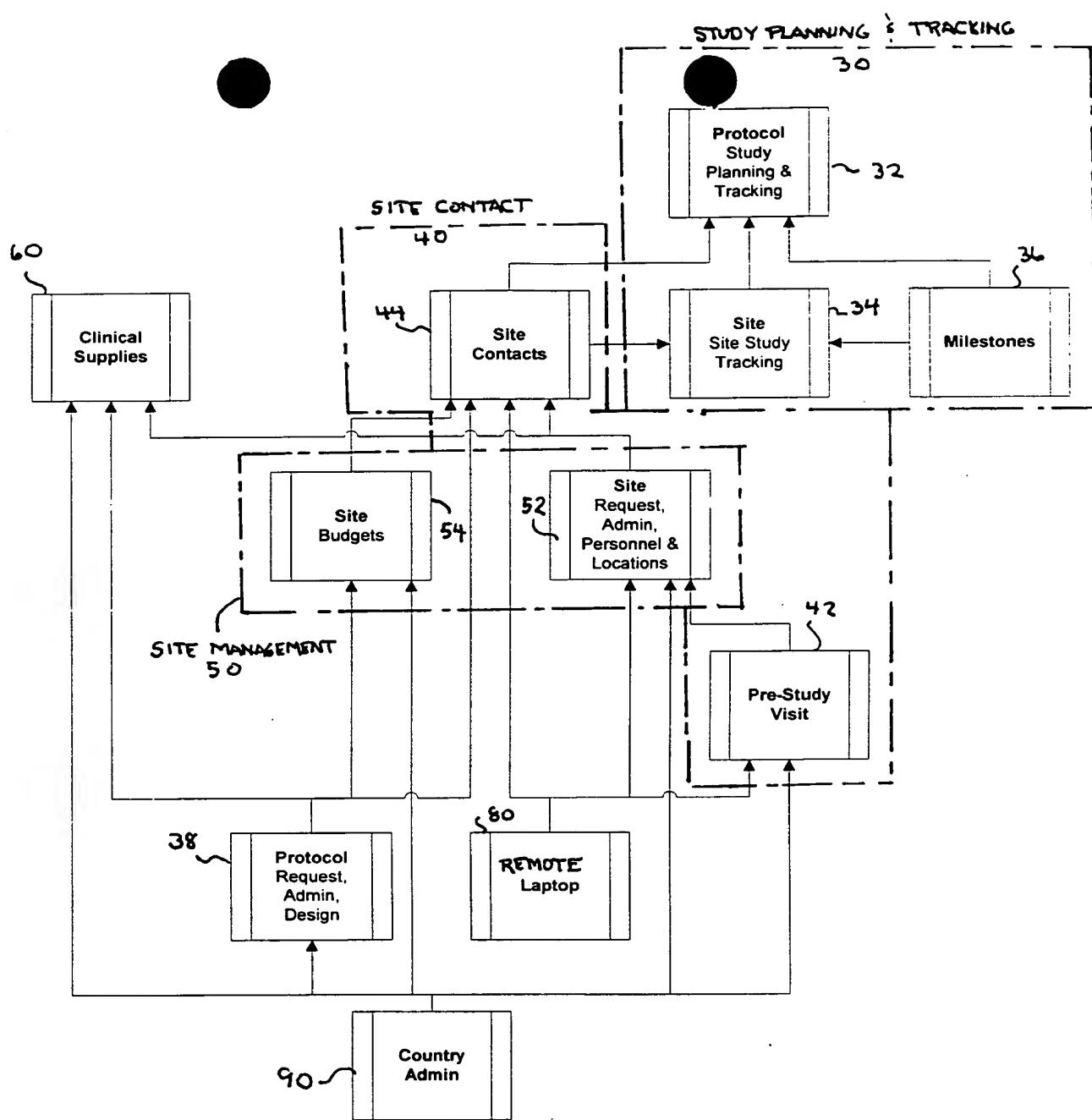
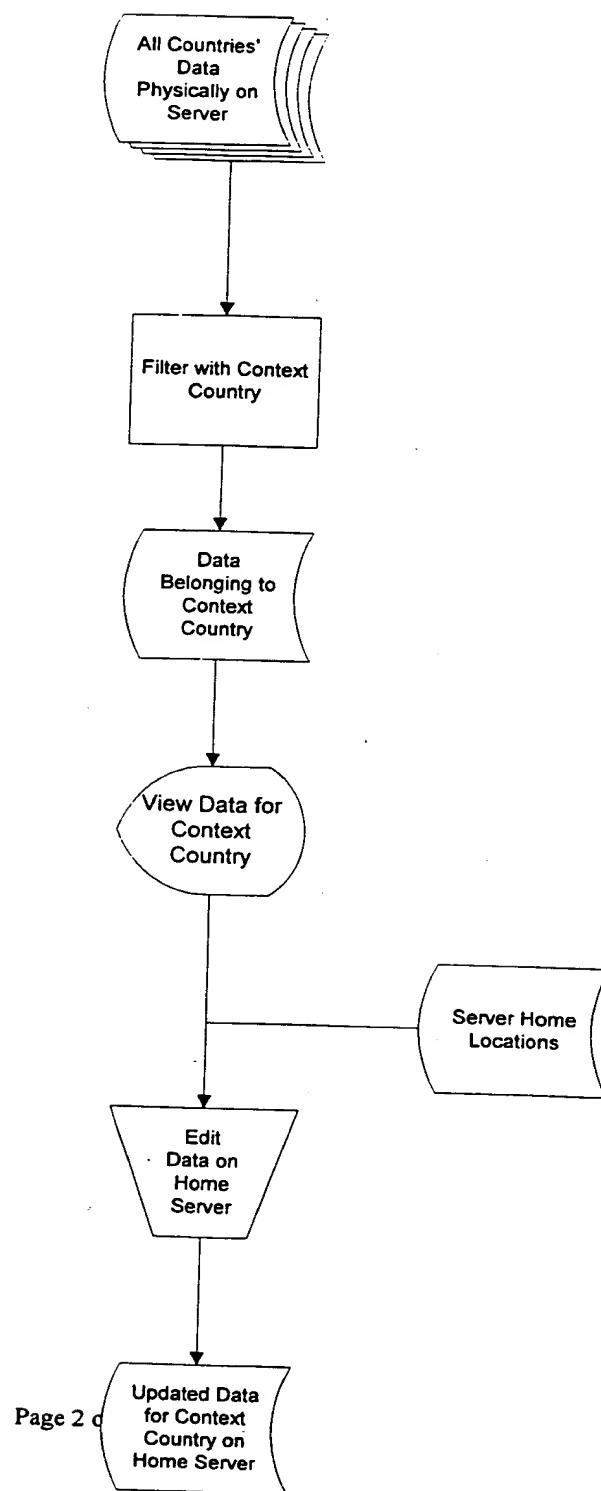


FIG. 2

**Data Flow Diagram**  
Module: **Architecture**  
Section: **Multi-Country**

Fig. 3



## THE PROTOCOL NUMBER REQUEST SCREEN

Fig. 4

Protocol Number Request		Protocol		Request		Administration		Design		Study Planning		Site Tracking		Protocol Number		Protocol Title		
Request ID	Subject	Site	Protocol	Site	Protocol	Site	Protocol	Site	Protocol	Site	Protocol	Site	Protocol	Site	Protocol	Site	Protocol	Site
RQ - 0000001	01-MAR-19	Laptop	Land	Pan, Peter J.	Darling, Wendy	Land	Pan, Peter J.	Darling, Wendy	Land	Pan, Peter J.	Darling, Wendy	Land	Pan, Peter J.	Darling, Wendy	Land	Pan, Peter J.	Darling, Wendy	
RQ - 0000002	26-MAR-19	Milestones	Land	Pan, Peter J.	Darling, Wendy	Land	Pan, Peter J.	Darling, Wendy	Land	Pan, Peter J.	Darling, Wendy	Land	Pan, Peter J.	Darling, Wendy	Land	Pan, Peter J.	Darling, Wendy	
RQ - 0000003	26-MAR-19	Clinical Supplies	Land	Pan, Peter J.	Darling, Wendy	Land	Pan, Peter J.	Darling, Wendy	Land	Pan, Peter J.	Darling, Wendy	Land	Pan, Peter J.	Darling, Wendy	Land	Pan, Peter J.	Darling, Wendy	
RQ - 0000004	26-MAR-19	Reports	Land	Pan, Peter J.	Darling, Wendy	Land	Pan, Peter J.	Darling, Wendy	Land	Pan, Peter J.	Darling, Wendy	Land	Pan, Peter J.	Darling, Wendy	Land	Pan, Peter J.	Darling, Wendy	
RQ - 0000005	26-MAR-1998	SUBMITTED	Never Never Land	Pan, Peter J.	Darling, Wendy	Pan, Peter J.	Darling, Wendy	Medicine, Chief	Pan, Peter J.	Darling, Wendy	Medicine, Chief	Pan, Peter J.	Darling, Wendy	Absorption, Metabolism and Excretion	Pan, Peter J.	Darling, Wendy	Effects of iHuL-10 on Cytochrome P	
RQ - 0000006	26-MAR-1998	SUBMITTED	Never Never Land	Pan, Peter J.	Darling, Wendy	Pan, Peter J.	Darling, Wendy	Medicine, Chief	Pan, Peter J.	Darling, Wendy	Medicine, Chief	Pan, Peter J.	Darling, Wendy	Endometrial Histologic Effects of Ova	Pan, Peter J.	Darling, Wendy	Comparison of Mometasone Furoate	
RQ - 0000007	26-MAR-1998	RETURNED	Never Never Land	Pan, Peter J.	Darling, Wendy	Pan, Peter J.	Darling, Wendy	Medicine, Chief	Pan, Peter J.	Darling, Wendy	Medicine, Chief	Pan, Peter J.	Darling, Wendy	Comparison of Mometasone Furoate	Pan, Peter J.	Darling, Wendy	Mometasone	
RQ - 0000010	31-MAR-1998	ASSIGNED	Never Never Land	Pan, Peter J.	Darling, Wendy	Pan, Peter J.	Darling, Wendy	Medicine, Chief	Pan, Peter J.	Darling, Wendy	Medicine, Chief	Pan, Peter J.	Darling, Wendy	Pan, Peter J.	Darling, Wendy	Pan, Peter J.	Mometasone vs. Budesonide in Asth	
RQ - 0000079	03-APR-1998	SUBMITTED	Never Never Land	Pan, Peter J.	Darling, Wendy	Pan, Peter J.	Darling, Wendy	Pan, Peter J.	Darling, Wendy	Pan, Peter J.	Darling, Wendy	Pan, Peter J.	Darling, Wendy	Pan, Peter J.	Darling, Wendy	Pan, Peter J.	Mometasone vs. Budesonide in Asth	
RQ - 0000080	08-APR-1998	ASSIGNED	Never Never Land	Pan, Peter J.	Darling, Wendy	Pan, Peter J.	Darling, Wendy	Pan, Peter J.	Darling, Wendy	Pan, Peter J.	Darling, Wendy	Pan, Peter J.	Darling, Wendy	Pan, Peter J.	Darling, Wendy	Pan, Peter J.	Mometasone vs. Budesonide in Asth	
RQ - 0000103	07-MAY-1998	SUBMITTED	Never Never Land	Pan, Peter J.	Darling, Wendy	Pan, Peter J.	Darling, Wendy	Pan, Peter J.	Darling, Wendy	Pan, Peter J.	Darling, Wendy	Pan, Peter J.	Darling, Wendy	Pan, Peter J.	Darling, Wendy	Pan, Peter J.	Mometasone vs. Budesonide in Asth	

09555657-090600

5/8/98 9:20:23

PROSIT - UNITED STATES

File Edit Actions Modules Window Help

Protocol Number Request Details [New]

Request No: Schering No: Submit Date: Status: NEW

Schering Name:

Requester: Rispoli, Marc C SPRI US IND:  International:

Project Physician:

Program:

Mktd. Dose Form:

Project Accounting Code:

Monitoring Area:

Expense Center: 1477 - RESEARCH SYS

Phase:

Protocol Type:

Working Title:

A/S S

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PROSIT - UNITED STATES

File Edit View Actions Modules Window Help

Protocol Administration 1 - P00324

Protocol: P00324 Schering No: 000049 Schering Name: ANTERON

Working Title: testing the new Prosit build version 1.04

Administration | Personnel | External Organizations |

- Protocol Status

Protocol Status: Amendment In Progress Study Status: PLANNED Active:

Finalize Date: 04-NOV-1998 Notification:  Notif. Date:

Notif. Reason: [ ]

Administration/Accounting

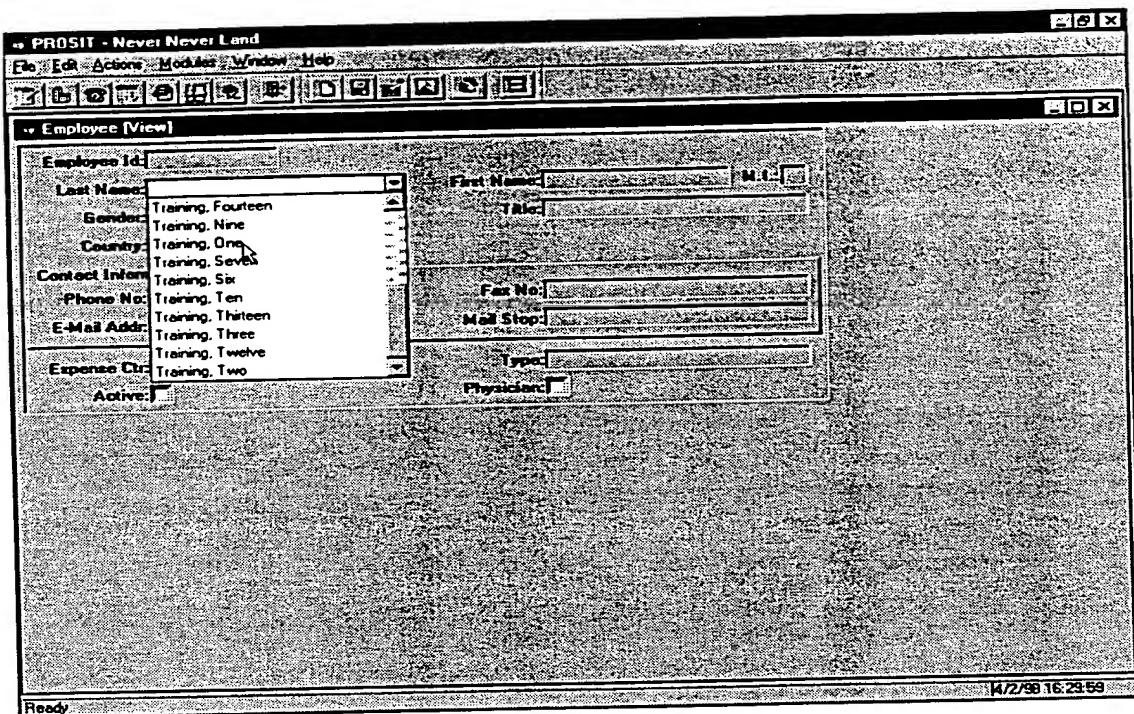
Therapeutic Team: [ ]	<input checked="" type="checkbox"/> Expense Center: 1477 - RESEARCH SYS
Program: INTERNATIONAL ALLERGY	Mixed Dose Form: ALKM SPNU
Project Acc. Code: FD1 - 000049 - 303E	Originating Sub: UNITED STATES
Monitoring Area: MEDICAL AND SCIENTIFIC AFFARS	Amend. Version: 1 Event Manager: <input checked="" type="checkbox"/>
Protocol Type: I-MEDICAL RESEARCH INTERNATIO	Final Amend. Date:

The name of an outside organization or company that is working with SP on some aspect of the study

05-Jan-1999

Fig. 6

## EMPLOYEE ROSTER SCREEN



## PROTOCOL DESIGN

PROSIT NEVER NEVER LAND

File Edit View Action Modules Window Help

Protocol Design > 000065 Schering No: 000065 Sourcing Name: MOMETASONE

Protocol: 000065 Schering No: 000065 Sourcing Name: MOMETASONE

Working Title: Mometasone vs. Budesonide in Asthma

Designs Medications Visit Map Procedures Optional Fields Subject Eligibility Study Objectives

Working Title: Mometasone vs. Budesonide in Asthma  
Protocol Title: Efficacy and safety of mometasone furoate dry powder and budesonide powder (pulmicort turbuhaler) in the treatment of asthma

Primary Indication: 493 ASTHMA Secondary Indications:  
IND/HA Ref No: Phase: PHASE III  
Study Population: ADULTS  
Data Collection Tool: CRF  
Synopsis:  
Salbutamol MDI acceptable for reversibility

This is a brief summary of the protocol

4/3/98 13:19:30

A.S. J.

0955336677 096600

## THE MEDICATION TAB

PROSIT - NEVER NEVER LAND

File Edit View Actions Modules Window Help

Protocol Design - 000065 Screening No: 032068 Screening Name: MDOMETASONE

Working Title: Monetasone vs. Placebo Author:

Design Medication Visit Map Procedure Optional Fields Subject Entry Study Objectives

Test Drug Number Test Drug Name Role Amendment ID

032068 MDOMETASONE PRIMARY

Test drug number can not be modified once saved; to change a test drug number delete it and re-add it.

Strength	Regimen	Dose Form	Route	Amendment ID
100 mcg	2x daily	INHAL PWD	INTRANASAL	
200 mcg	2 or 4x daily	INHAL PWD	INTRANASAL	
4				

Ready 4/3/98 13:30:32

F. S. 9

## VISIT MAP

PROSIT - NEVER NEVER LAND

File Edit View Actions Modules Window Help

Protocol Design: - 000065 Schering No: 032089 Schering Name: MOMETASONE

Working Title: Montelazone vs. Budesonide in Asthma

Design Medication Visit Map Procedures Optional Fields Subject Eligibility Study Objectives

Visit Visit Label	Study Phase	Prev Visit ID	Date Since Prior Visit Min	Date Since Prior Visit Max	Enrollment Assignment ID
V1 Test Recruitment	SCREENING		0	0	
V2 Baseline	TREATMENT	1	7	14	
V3 1st Evaluation	TREATMENT	2	5	5	
V4 2nd Evaluation	TREATMENT	3	5	5	
V5 Final Evaluation	FOLLOW-UP	4	25	31	
V6 1st Evaluation Short	TREATMENT	2	7	14	
V7 Final Evaluation Short	FOLLOW-UP	6	25	31	
V8		7			

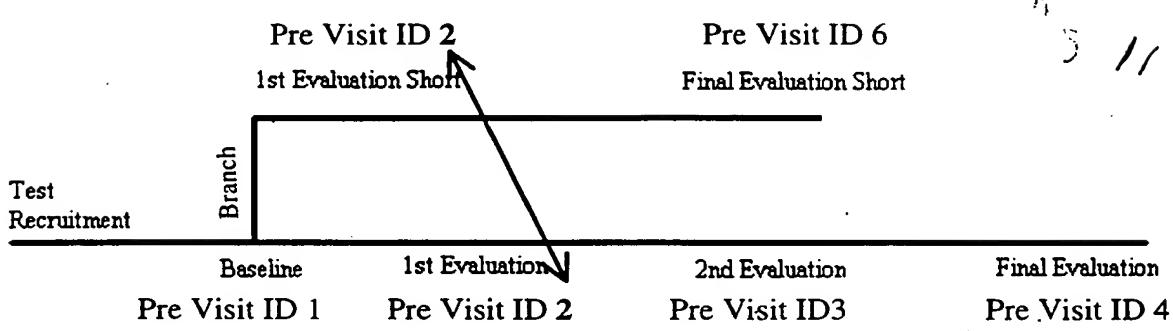
This is a descriptive label for the visit.

4/3/98 12:39:00

T/S 10

09655667 090600

## **DIFFERENT TREATMENT SCHEDULES CONT.**



## PROCEDURES TAB

PROSIT - Never Never Land

File Edit View Actions Modules Window Help

Protocol: \* - 000065 Schering No: 022080 Schering Name: MOMETASONE

Working Title: Mometasone vs. Budesonide in Asthma

Design Medication Visit Map Procedures Optional Fields Subject Eligibility Study Objectives Treatment Schedule Treatment Schedule 1

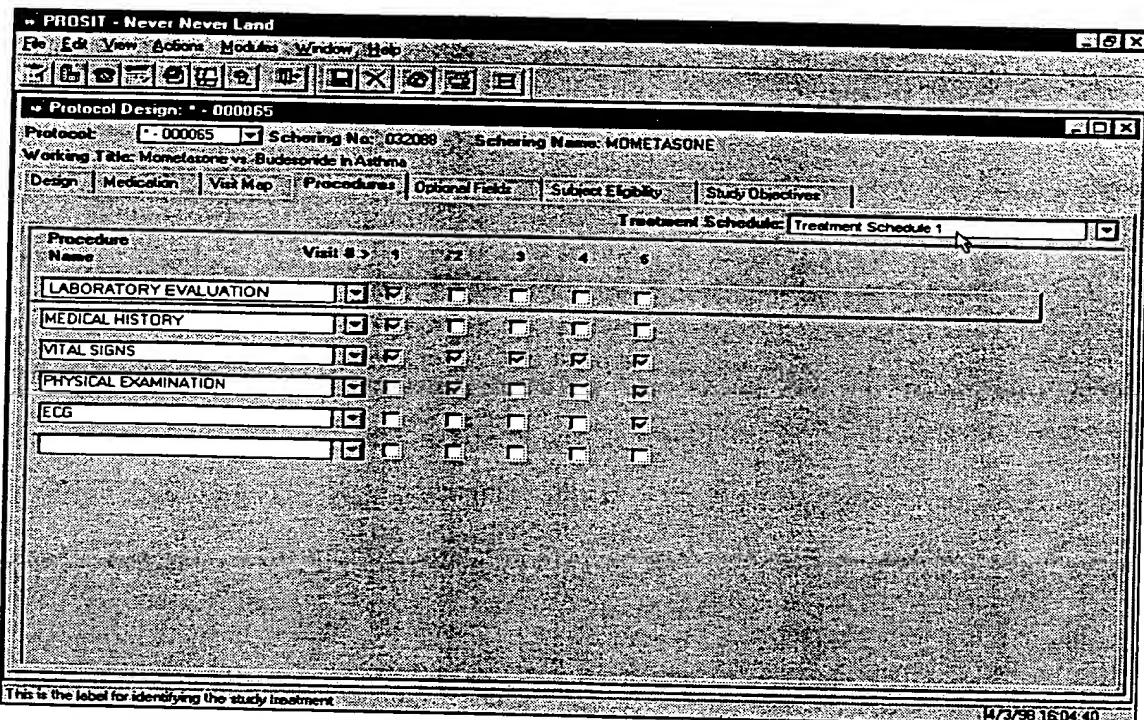
Procedure Name Visit 0 > 1 2 3 4 5

LABORATORY EVALUATION	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
MEDICAL HISTORY	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
VITAL SIGNS	<input checked="" type="checkbox"/>				
PHYSICAL EXAMINATION	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
ECG	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>

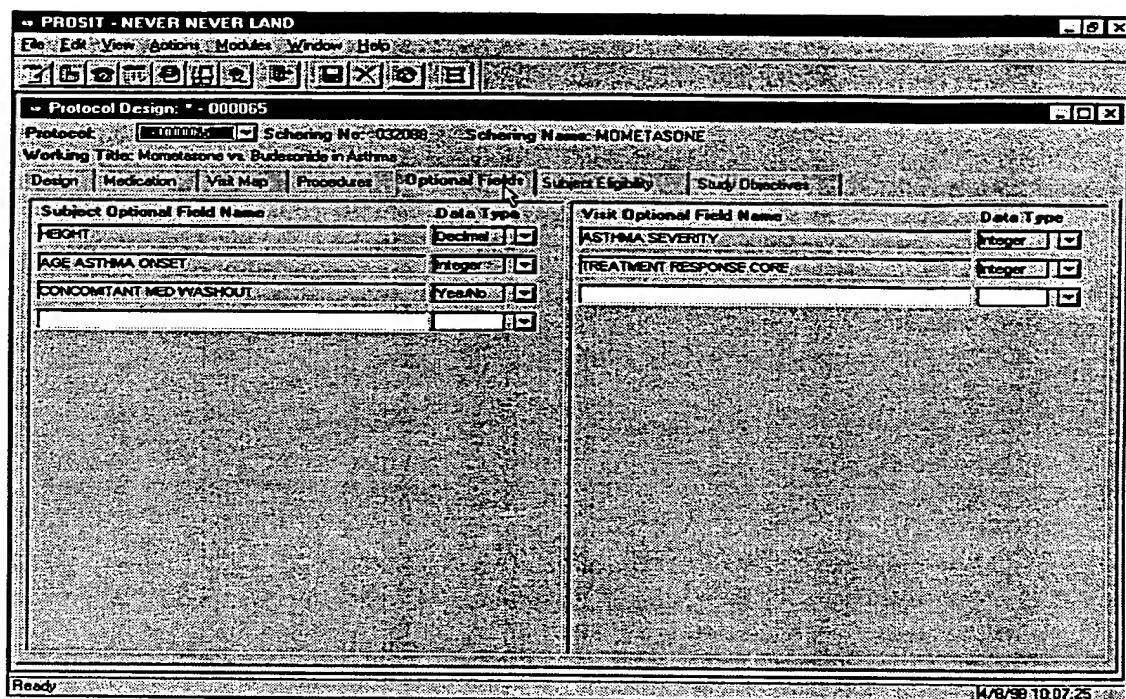
This is the label for identifying the study treatment

4/3/98 16:04:40

A. S. 12



## OPTIONAL FIELDS



09555667 090600

## SUBJECT ELIGIBILITY

PROSIT - Never Never Land

File Edit View Actions Modules Window Help

Protocol Design: P00008 Screening No.: 032098 Screening Name: MOMETASONE

Working Title: Mometasone vs Budesonide in Asthma

Design Medications Visit Map Procedures Optional Fields Subject Eligibility Study Objectives

Reason for Ineligibility

EXCLUDED CONCOMITANT MEDICATION  
DO NOT MEET ENTRANCE CRITERIA  
SUBJECT DOES NOT WISH TO PARTICIPATE  
EXCLUDED CONCOMITANT ILLNESS

Reason for Discontinuation

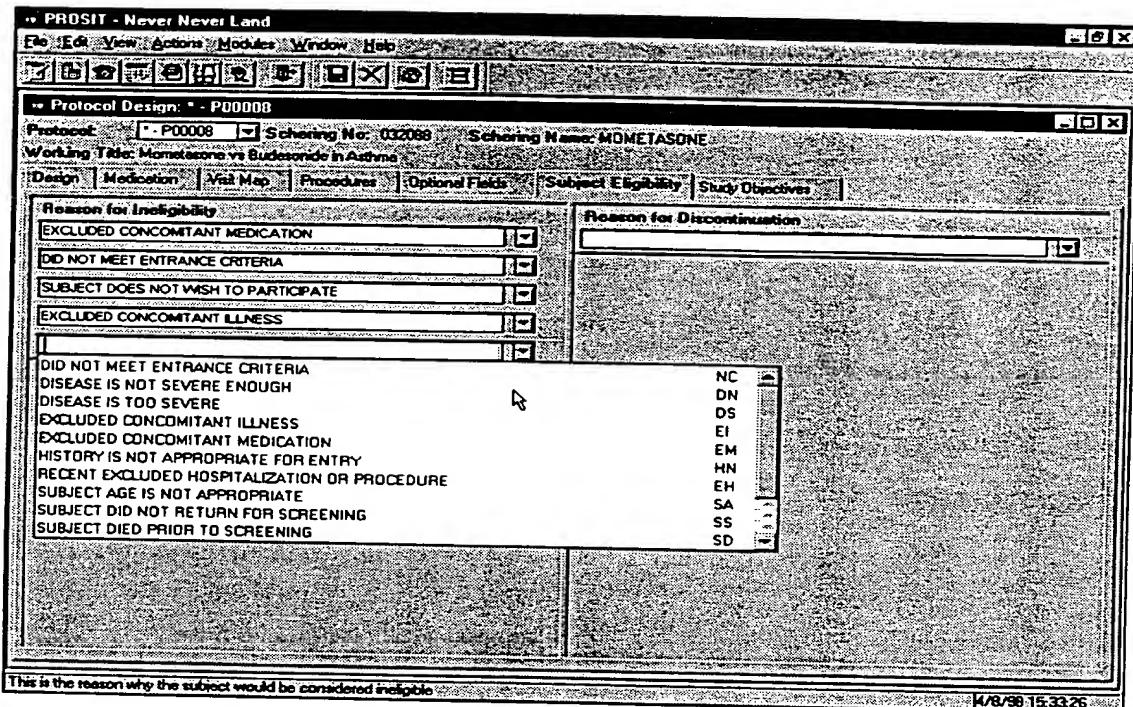
DID NOT MEET ENTRANCE CRITERIA  
DISEASE IS NOT SEVERE ENOUGH  
DISEASE IS TOO SEVERE  
EXCLUDED CONCOMITANT ILLNESS  
EXCLUDED CONCOMITANT MEDICATION  
HISTORY IS NOT APPROPRIATE FOR ENTRY  
RECENT EXCLUDED HOSPITALIZATION OR PROCEDURE  
SUBJECT AGE IS NOT APPROPRIATE  
SUBJECT DID NOT RETURN FOR SCREENING  
SUBJECT DIED PRIOR TO SCREENING

NC  
DN  
DS  
EI  
EM  
HN  
EH  
SA  
SS  
SD

This is the reason why the subject would be considered ineligible

4/8/98 15:33:26

A.S. 14



## REASONS FOR DISCONTINUATION CONT.

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1.5.15

.. PROSIT - Never Never Land

File Edit View Options Modules Window Help

Protocol: P00008 Schering No: ICZ008 Schering Name: MOMETASONE

Working Title: Mometasone vs Budesonide in Asthma

Design Medication Visit Map Procedures Optional Fields Subject Eligibility Study Objectives

Reason for Ineligibility

EXCLUDED CONCOMITANT MEDICATION	<input type="checkbox"/>
PREGNANCY	<input type="checkbox"/>
DISEASE IS TOO SEVERE	<input type="checkbox"/>

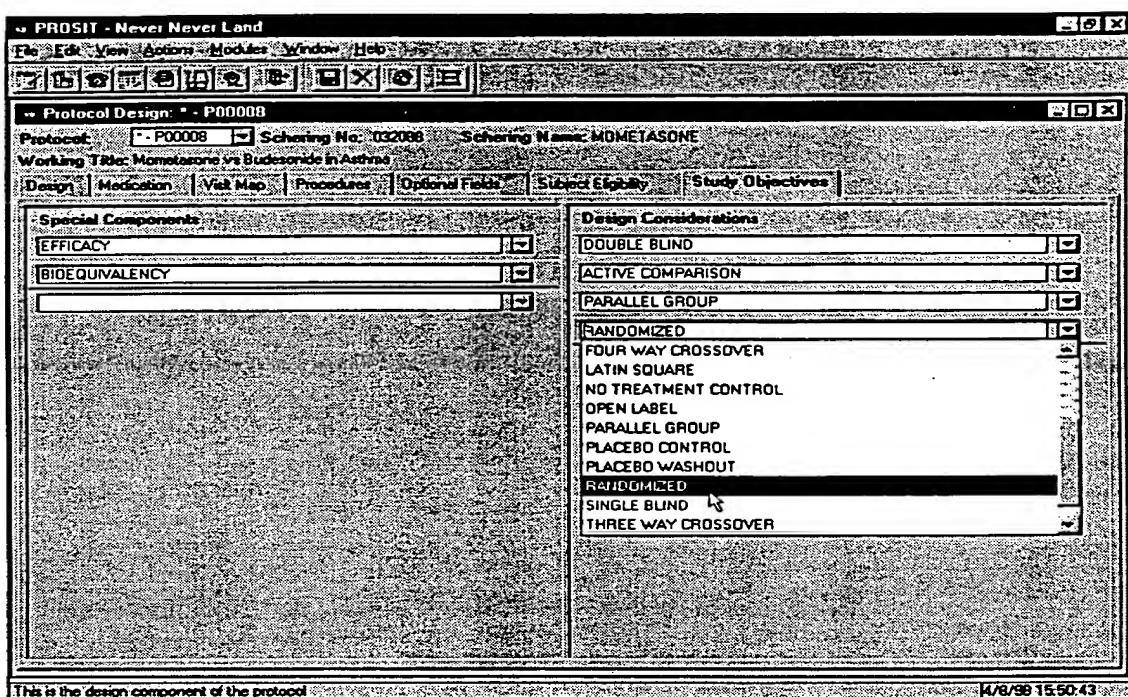
Reason for Discontinuation

ADVERSE EVENT	<input type="checkbox"/>
PRE-ATRO	<input type="checkbox"/>
TREATMENT FAILURE, OVERALL DX STATUS MOD/SEVERE	<input type="checkbox"/>
LOST TO FOLLOWUP	<input type="checkbox"/>
INVESTIGATOR DEEMS IT IS NOT IN SUBJECTS BEST INTERES	<input type="checkbox"/>
NON-COMPLIANCE	<input type="checkbox"/>
DID NOT MEET PROTOCOL ELIGIBILITY	<input type="checkbox"/>

ADMINISTRATIVE	70
ADVERSE EVENT	10
CLEARED	80
COMPLETE	00
DEATH	99
DID NOT ENTER NEXT PHASE	51
DID NOT MEET CROSSOVER REQUIREMENTS	64
DID NOT MEET PROTOCOL ELIGIBILITY	60
DID NOT MEET PROTOCOL REQUIREMENTS	63
DID NOT MEET RANDOMIZATION CRITERIA	65

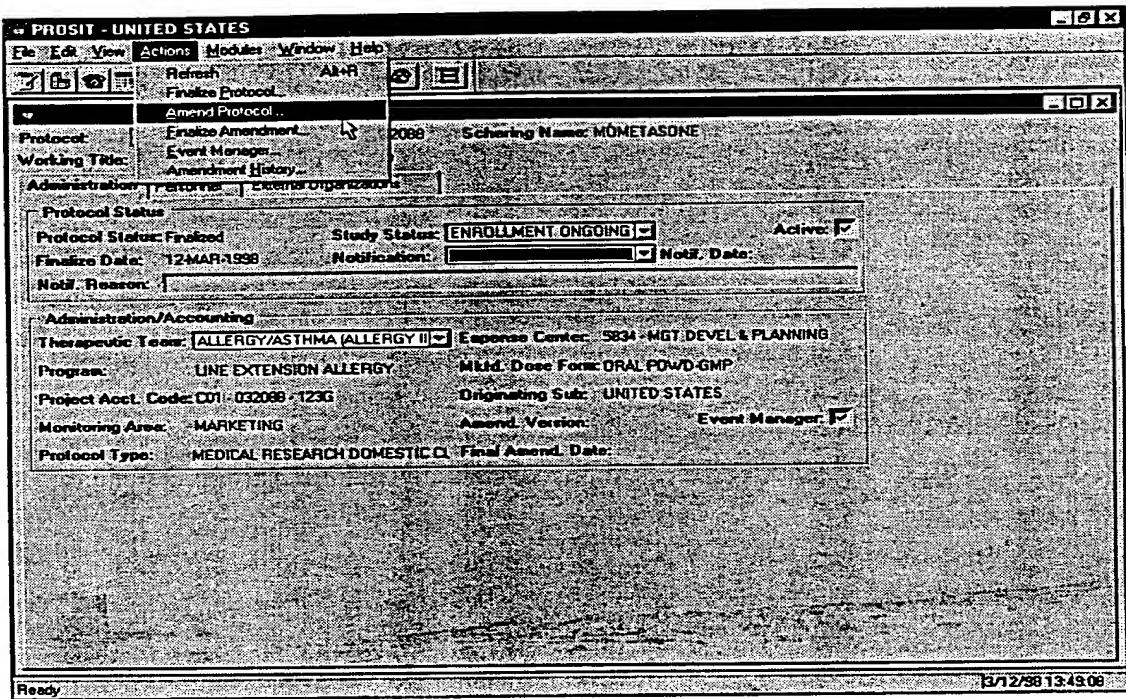
This is the reasons why a subject would be discontinued 14/6/98 15:48:13

## DESIGN CONSIDERATIONS



09555667 090600

## **CREATING AN AMENDMENT**



T-S. 18

Seq	Task Name	Type	Task ID	Milestone Indicator		
1	Completion of Clinical Program	SIMPLE	50	<input checked="" type="checkbox"/>		
2	Investigator Agreement Sent to HQ.	SIMPLE	23	<input checked="" type="checkbox"/>		
3	Curriculum Vitae of Principal Investigator(s)	SIMPLE	39	<input checked="" type="checkbox"/>		
4	CV of Laboratory Director(s) Received in S	SIMPLE	43	<input checked="" type="checkbox"/>		
5	Informed Consent Task(Trans)	SIMPLE	26	<input checked="" type="checkbox"/>		
6	Gov. Regulatory App. (w/trans.) Received in S	SIMPLE	30	<input checked="" type="checkbox"/>		
7	CV of Laboratory Director(s) Received in Sub.	SIMPLE	34	<input checked="" type="checkbox"/>		
8	this is a new master task that was created by mark fung-a	SIMPLE	130	<input checked="" type="checkbox"/>		
9	this is another very long task name that was created on the s	SIMPLE	141	<input checked="" type="checkbox"/>		
10	Site Administration	SIMPLE	47	<input checked="" type="checkbox"/>		
11	Site Administration -Location\Personnel	SIMPLE	48	<input checked="" type="checkbox"/>		
12	Site Administration -Personnel and location	SIMPLE	457	<input checked="" type="checkbox"/>		
13	mark	SIMPLE	248	<input checked="" type="checkbox"/>		
14	Site Administration	SIMPLE	49	<input checked="" type="checkbox"/>		
15	First Data Discrepancy Report Available	SIMPLE	523	<input checked="" type="checkbox"/>		
16	Master Task Comm	SIMPLE	559	<input checked="" type="checkbox"/>		
17	First Subject/First Visit (Protocol)	SIMPLE	570	<input checked="" type="checkbox"/>		
18	Root	SIMPLE	20	<input checked="" type="checkbox"/>		
19	Design Start	SIMPLE	48	<input checked="" type="checkbox"/>		
20	Primary Stat Analysis Results Released	SIMPLE	15	<input checked="" type="checkbox"/>		

Rollup Task Name	Type	System ID

(Ready)

05-Jan-1999

Fig. 19

**Core Task List**

Seq#	Name	Task Type	Milestone Indicator
1.	Protocol Number Assigned	EVENT-MANAGER SIMPLE	<input checked="" type="checkbox"/>
2.	Final Protocol Date	EVENT-MANAGER SIMPLE	<input checked="" type="checkbox"/>
3.	Final CRF/RDE Screens Available	SIMPLE	<input checked="" type="checkbox"/>
4.	First Site Initiated	SUMMARY	<input checked="" type="checkbox"/>
5.	First Subject Enrolled(Protocol)	SUMMARY	<input checked="" type="checkbox"/>
6.	First Subject First Visit	SUMMARY	<input checked="" type="checkbox"/>
7.	Enrollment Cutoff (Protocol)	EVENT-MANAGER SIMPLE	<input checked="" type="checkbox"/>
8.	Last Subject / Last Visit (Protocol)	EVENT-MANAGER SIMPLE	<input checked="" type="checkbox"/>
9.	Last CIVE/Data Discrepancy In-House	SIMPLE	<input checked="" type="checkbox"/>
10.	Data Cleanup Complete (Protocol)	EVENT-MANAGER SIMPLE	<input checked="" type="checkbox"/>
11.	Database Locked	EVENT-MANAGER SIMPLE	<input checked="" type="checkbox"/>
12.	Primary Stat Analysis Results Released	SIMPLE	<input checked="" type="checkbox"/>
13.	Final Statistical Results Released	SIMPLE	<input checked="" type="checkbox"/>
14.	Final Data Listings Released	SIMPLE	<input checked="" type="checkbox"/>
15.	Final PCS Date	SIMPLE	<input checked="" type="checkbox"/>
16.	Last Data In-house/SPRI HQ(Protocol)	EVENT-MANAGER SIMPLE	<input checked="" type="checkbox"/>
17.	Last Site Initiated [to Date]	SUMMARY	<input checked="" type="checkbox"/>
18.	(New)		

A description of a task that will be mandatory for inclusion in every site plan in this country.

115.20

Seq.	Task Name	Task Type Process Name	Milestone Indicator	NTA Indicator
24	Prestudy Visit Form(s) Received in Subsidiy	SIMPLE	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
25	Prestudy Visit Form(s) Sent to HQ.	SIMPLE	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
26	Protocol Signed by Investigator Rec. in Sub.	SIMPLE	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
27	First Subject Enrolled (Site)	AUTOMATIC ROLL-UP	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
28	Protocol Signed by Investigator Sent to HQ.	SIMPLE	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
29	Site Initiated	AUTOMATIC ROLL-UP	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
30	First Subject Screened	AUTOMATIC ROLL-UP	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
31	All Data In-house (Site)	MANUAL ROLL-UP	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
32	Written Ethics Committee App. (w/trans) Sent	SIMPLE	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
33	Written Ethics Committee App. (w/trans.) Rec.	SIMPLE	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
34	Data Clean-up Complete (Site)	MANUAL ROLL-UP	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
35	Enrollment Complete (Site)	MANUAL ROLL-UP	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
36	this is a new master task that was created by mark fun	SIMPLE	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
37	new requirement	SIMPLE	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
38	Site Administration -Personnel and location	SIMPLE	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
39	Site Administration	SIMPLE	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
40	Site Administration	SIMPLE	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
41	this is another very long task name that was created on	SIMPLE	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
42	Milestone task added to check the duration	SIMPLE	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
43	A master task with the milestone indc	SIMPLE	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
44	(New)			

A description of a task that will be mandatory for inclusion in every site plan in this country.

05-Jan-1999

F.S. 21

**PROSIT - UNITED STATES**

File Edit Actions Modules Window Help

Template: 1352 Changed: 12/17/98 Country: UNITED STATES

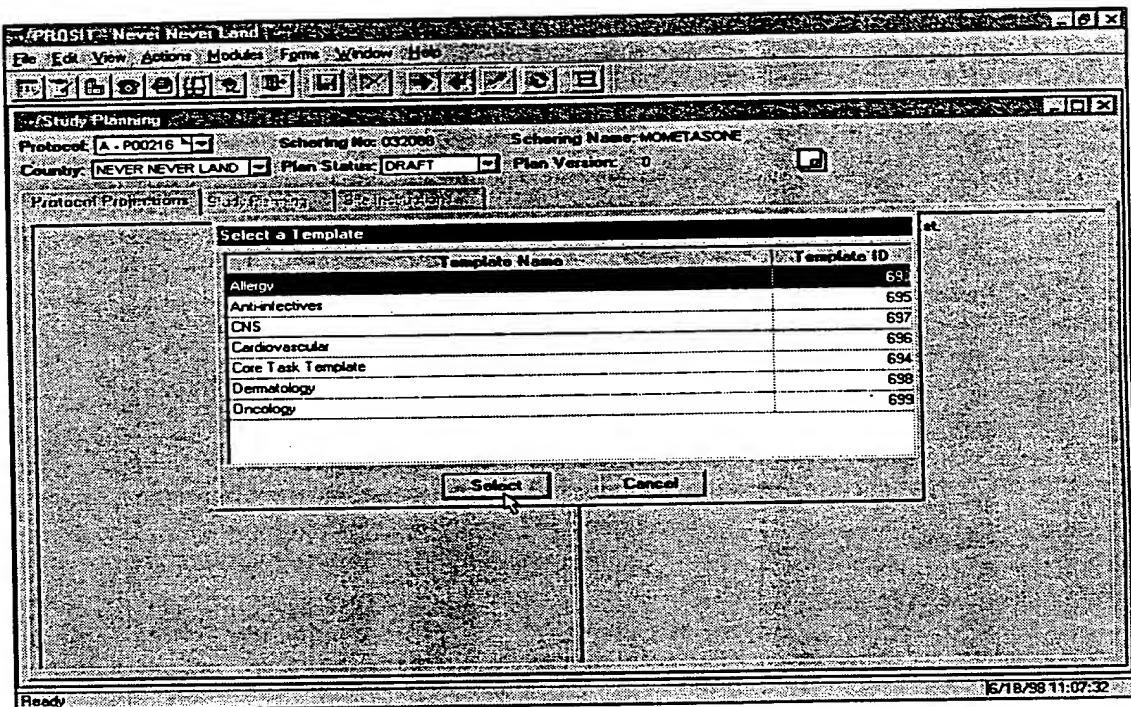
Template to test the milestone indic change

Seq#	Task Name	Days	Task Type	Milestone Indicator
1	USA-Template to test the milestone indic change	-1	USER DEFINED	
2	Protocol Number Assigned	-1	EVENT MANAGER SP	
3	Final Protocol Date	0	SIMPLE	
4	Final CRF/RDE Screen Date	0	SIMPLE	
5	First Site Initiated	0	SUMMARY	
6	First Subject/First Visit (Protocol)	0	SIMPLE	
7	Enrollment Complete (Protocol)	0	EVENT MANAGER SP	
8	Last Subject/ Last Visit (Protocol)	0	EVENT MANAGER SP	
9	Data Cleanup Complete (Protocol)	0	EVENT MANAGER SP	
10	Last Data Discrepancy Resolved	0	SIMPLE	
11	Database Locked	0	EVENT MANAGER SP	
12	Primary Stat Analysis Results Released	0	SIMPLE	
13	Final Statistical Results Released	0	SIMPLE	
14	Final Data Listings Released	1	SIMPLE	
15	Final PCS Date	0	SIMPLE	
16	First Subject Enrolled	0	SUMMARY	
17	First Subject First Visit	0	SUMMARY	
18	Budget Info.Sheet (signed&dated by Inv.) Rec.	0	SIMPLE	

A unique number assigned by the system to identify the template

05-Jan-1999

## SELECTING A TEMPLATE



0965567 - 096500

## PROTOCOL PROJECTION TAB

PROSIT - Never Never Land

File Edit View Actions Modules Forms Window Help

Protocol: A - P00216 | Screening No: 000088 | Screening Name: HOMETASONE

Country: NEVER NEVER LAND | Plan Status: DRAFT | Plan Version: 1.0

Protocol Projections | Study Planning | Site Instructions

Planned | Latest Est.

Evaluable Subjects	40
Subjects to Enroll	50
Sites NEVER NEVER LAND	2
Sites International	0
Sites Per Monitor	2
Sites Per HQ CRA	0
Monitoring Interval w/o	6
Min No Subjects Per Site	25
Average Subjects Per Site	40

Monitoring Countries | Planned | Latest Est.

NEVER NEVER LAND	0	0
Total	0	0

Ready 6/18/98 11:09:21

1/5  
22

# STUDY PLAN

F. S 24

Seq.	Task ID	Planned Start D	Planned End D	Planned Min Delay	Actual Start D	Actual End D	Actual Max Delay	Actual Min Delay
1	NP00216 - RNL	18-JUN-1998	18-JUN-1998	0	18-JUN-1998	18-JUN-1998	0	0
2	Protocol Number Assigned	18-JUN-1998	18-JUN-1998	0	18-JUN-1998	18-JUN-1998	0	0
3	Protocol Approved	00-0000	00-0000	0	00-0000	00-0000	0	0
4	Investigator Identified	00-0000	00-0000	0	00-0000	00-0000	0	0
5	Pre-Study visits Conducted	00-0000	00-0000	1	00-0000	00-0000	1	0
6	Last Pre-Study Visit Report C	00-0000	00-0000	0	00-0000	00-0000	0	0
7	First Site Initiated	00-0000	00-0000	0	00-0000	00-0000	0	0
8	First Subject First Visit	00-0000	00-0000	0	00-0000	00-0000	0	0
9	Enrollment Complete (Protocol)	00-0000	00-0000	0	00-0000	00-0000	0	0
10	Last Subject/ Last Visit (Protocol)	00-0000	00-0000	0	00-0000	00-0000	0	0
11	All Data In-house (Protocol)	00-0000	00-0000	0	00-0000	00-0000	0	0
12	Database Locked	00-0000	00-0000	0	00-0000	00-0000	0	0
13	Primary Stat Analysis Results Re	00-0000	00-0000	0	00-0000	00-0000	0	0
14	Protocol Analysis Final	00-0000	00-0000	0	00-0000	00-0000	0	0
15	CSR Approved	00-0000	00-0000	0	00-0000	00-0000	0	0
16	(New)	00-0000	00-0000	1	00-0000	00-0000	1	0

Ready 6/18/98 11:15:05

F5. 25

**PROSIT - Never Never Land**

File Edit View Actions Modules Forms Window Help

Protocol: P-P00124 Schering No: 000105 Schering Name: ESTRADOL  
 County: NeverNever Land Plan Status: DRAFT Plan Version: 0

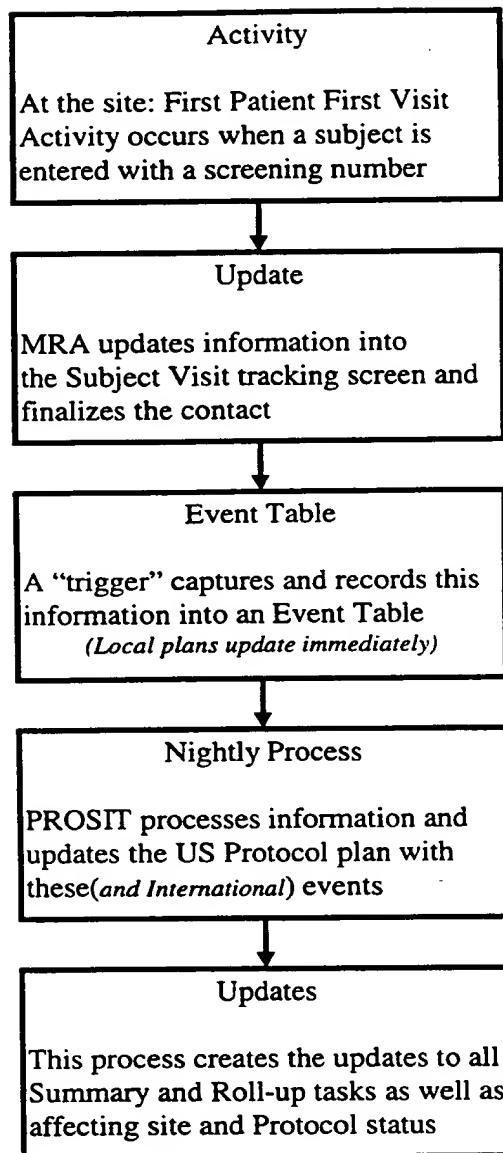
Study Planning Site Instructions Protocol Projections SMP Study Plan SMP Site Instructions

Seq	Task Name	Planned Start D	Planned End D	Planned Min Delay	Latest Start D	Latest End D	Latest Days	Latest Min Delay
1	P00124 - USA	12-AUG-1999	12-AUG-1999	0	12-AUG-1999	12-AUG-1999	0	
2	Protocol Number Assigned	12-AUG-1999	12-AUG-1999	0	12-AUG-1999	12-AUG-1999	0	
3	Final Protocol Date	00-0000	00-0000	0	00-0000	00-0000	0	0
4	Final CRF/RDE Screens Available	00-0000	00-0000	0	00-0000	00-0000	0	0
5	First Site Initiated	00-0000	00-0000	0	00-0000	00-0000	0	0
6	First Subject Enrolled(Protocol)	00-0000	00-0000	0	00-0000	00-0000	0	0
7	First Subject, First Visit	00-0000	00-0000	0	00-0000	00-0000	0	0
8	Enrollment Cutoff (Protocol)	00-0000	00-0000	0	00-0000	00-0000	0	0
9	Last Subject / Last Visit (Protocol)	00-0000	00-0000	0	00-0000	00-0000	0	0
10	Last CIVE/Data Discrepancy In-Ho	00-0000	00-0000	0	00-0000	00-0000	0	0
11	Data Cleanup Complete (Protocol)	00-0000	00-0000	0	00-0000	00-0000	0	0
12	Database Locked	00-0000	00-0000	0	00-0000	00-0000	0	0
13	Primary Stat Analysis Results Re	00-0000	00-0000	5	00-0000	00-0000	5	0
14	Final Statistical Results Release	00-0000	00-0000	0	00-0000	00-0000	0	0
15	Final Data Listings Released	00-0000	00-0000	0	00-0000	00-0000	0	0

The country whose plan will be viewed and/or edited

12-Aug-1999

## THE EVENT MANAGER



Module: Event Manager

PROSIT driven for:  
• Planned/Protocol Number Assigned

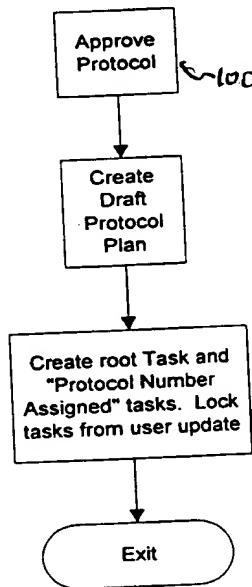


Fig. 27a

PROSIT driven for:  
• Protocol Approved

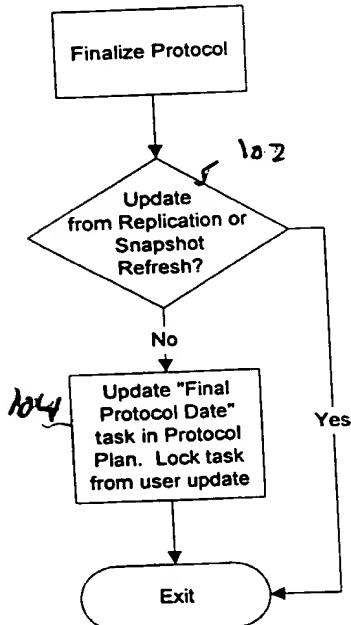


Fig. 27b

**Module: Event Manager**

PROSIT driven for:

- Initiated/1<sup>st</sup> Site Initiated & Site Initiated

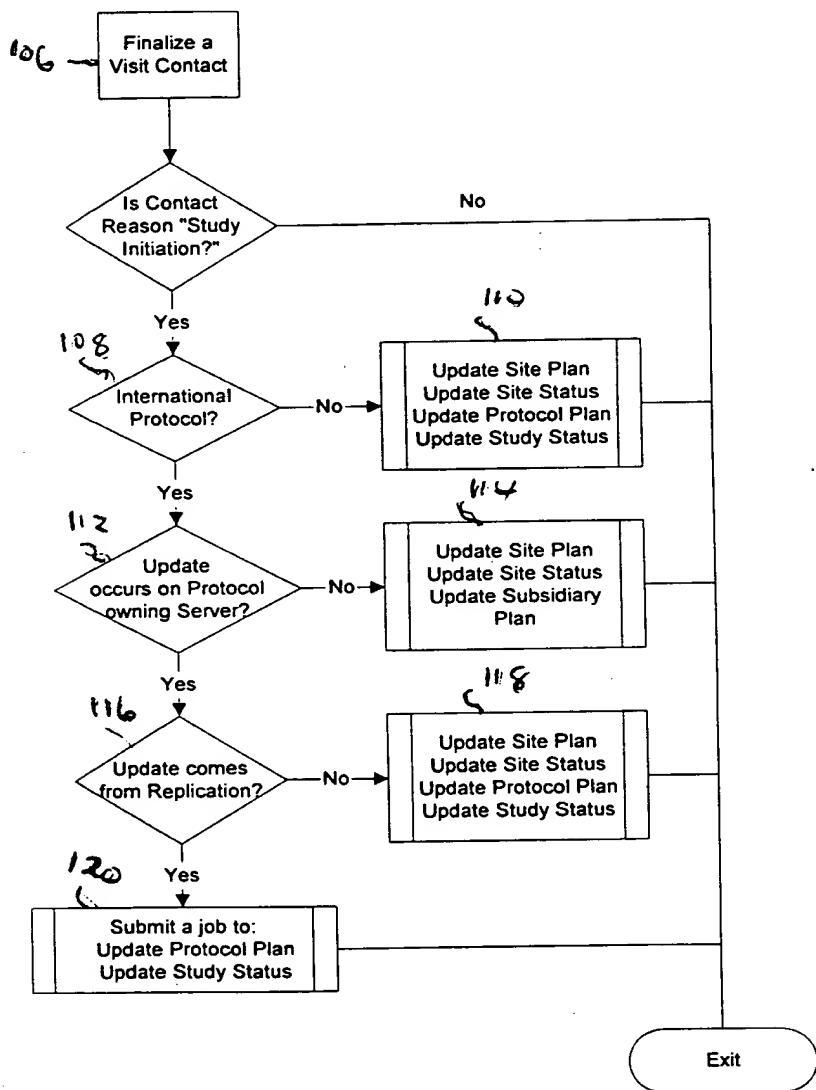
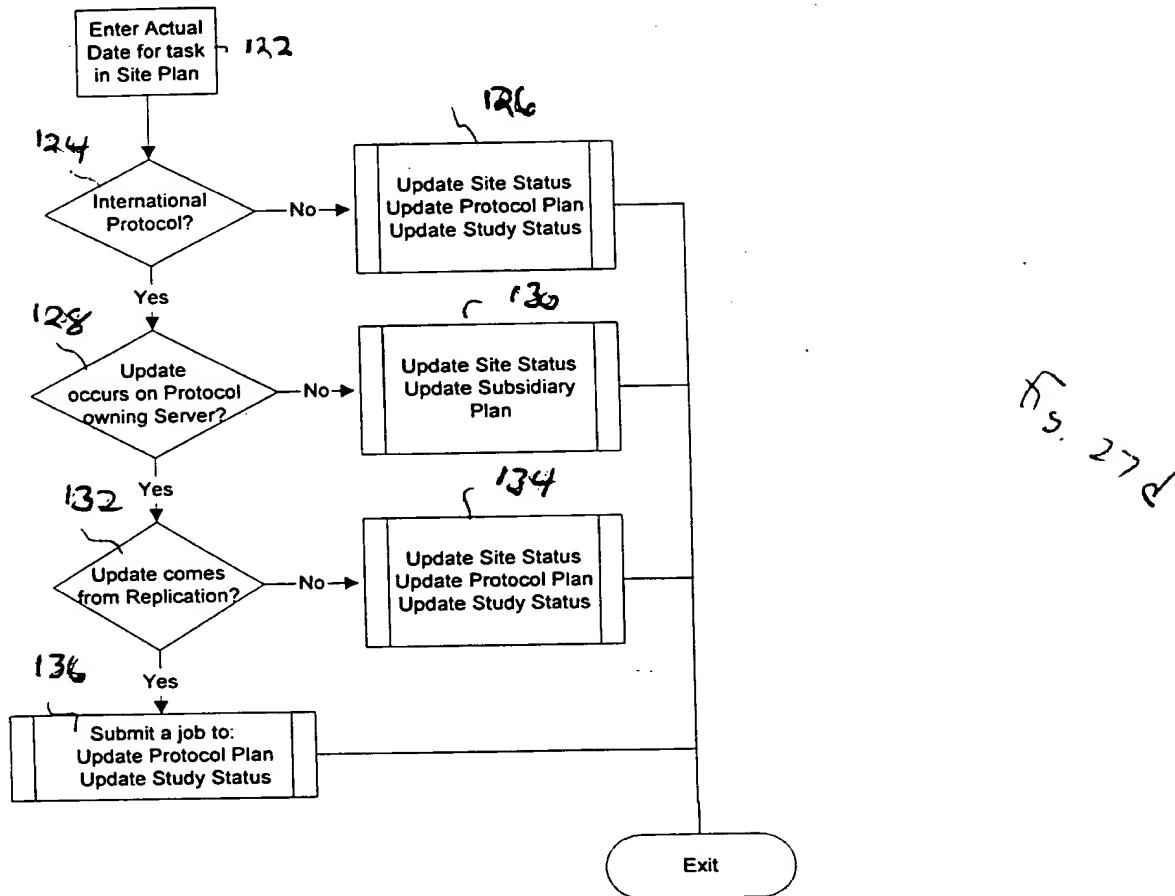


fig. 27c

Module: Event Manager

Milestone (site level) driven for:

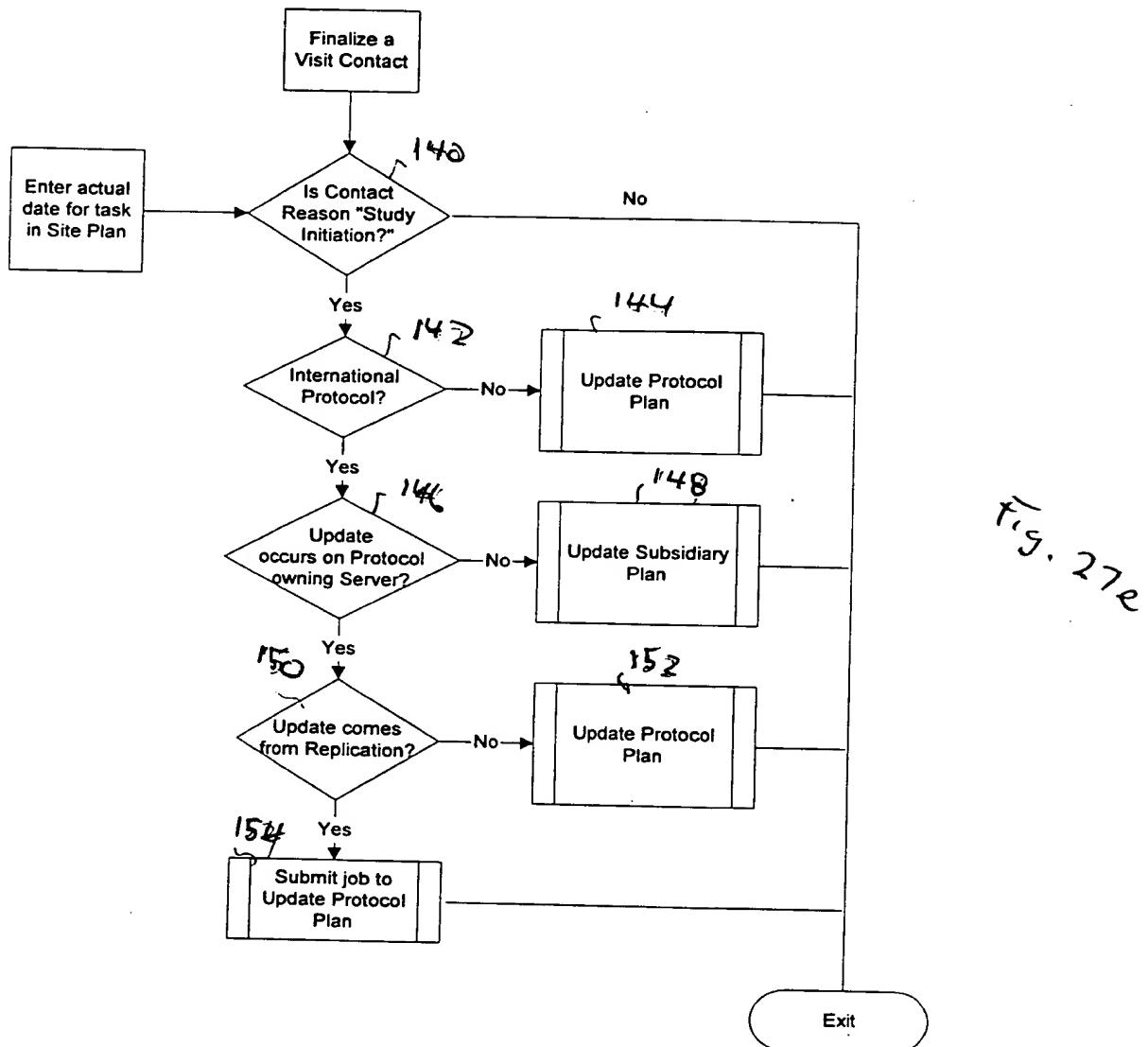
- Initiated/1<sup>st</sup> Site Initiated & Site Initiated
- Screening Ongoing/First Subject, First Visit
- Enrollment Ongoing/First Subject Enrolled



## **Module: Event Manager**

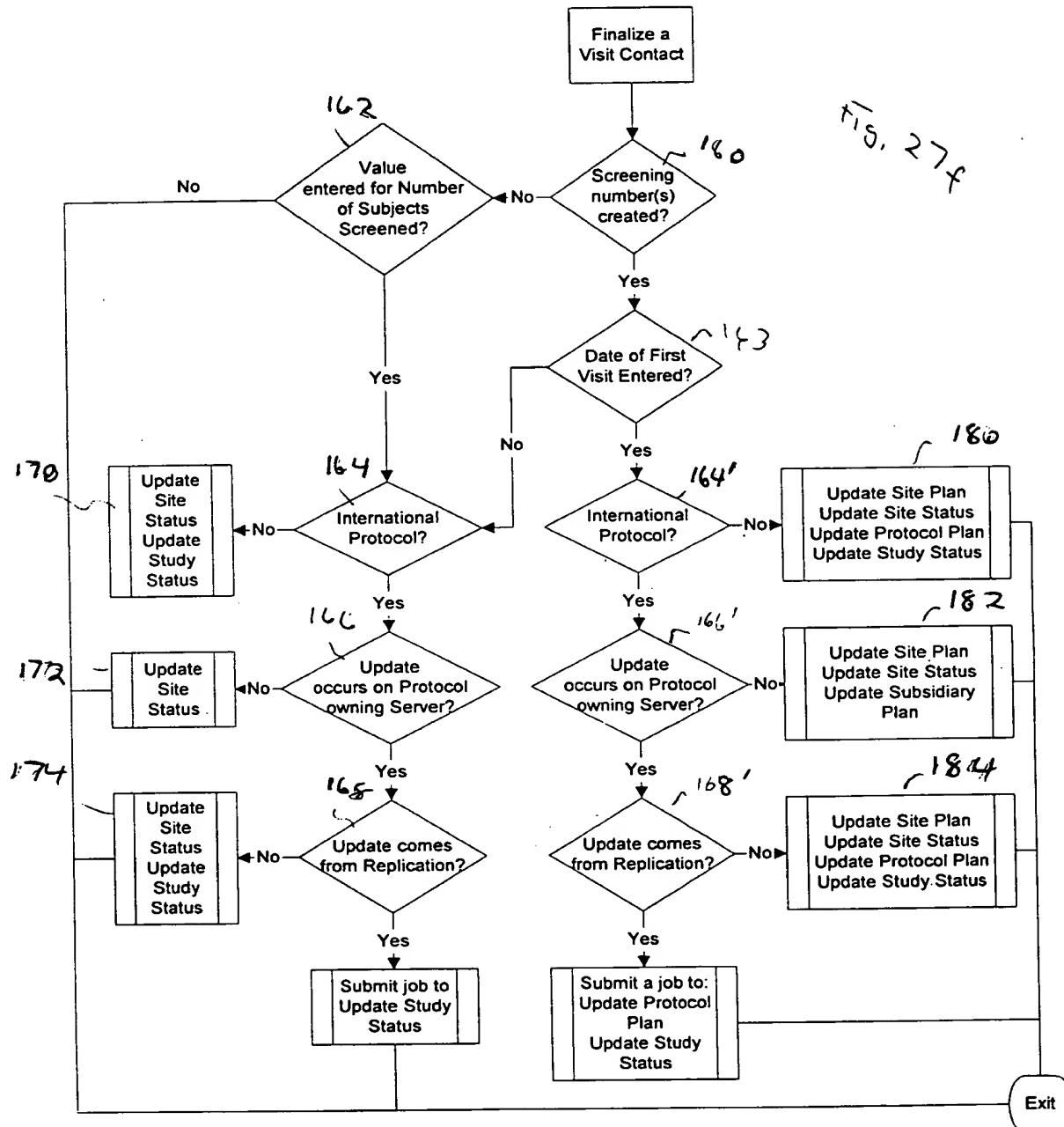
PROSIT and Milestone driven for:  
• Last Site Initiated (to Date)

- Last Site Initiated (to Date)



## Module: Event Manager

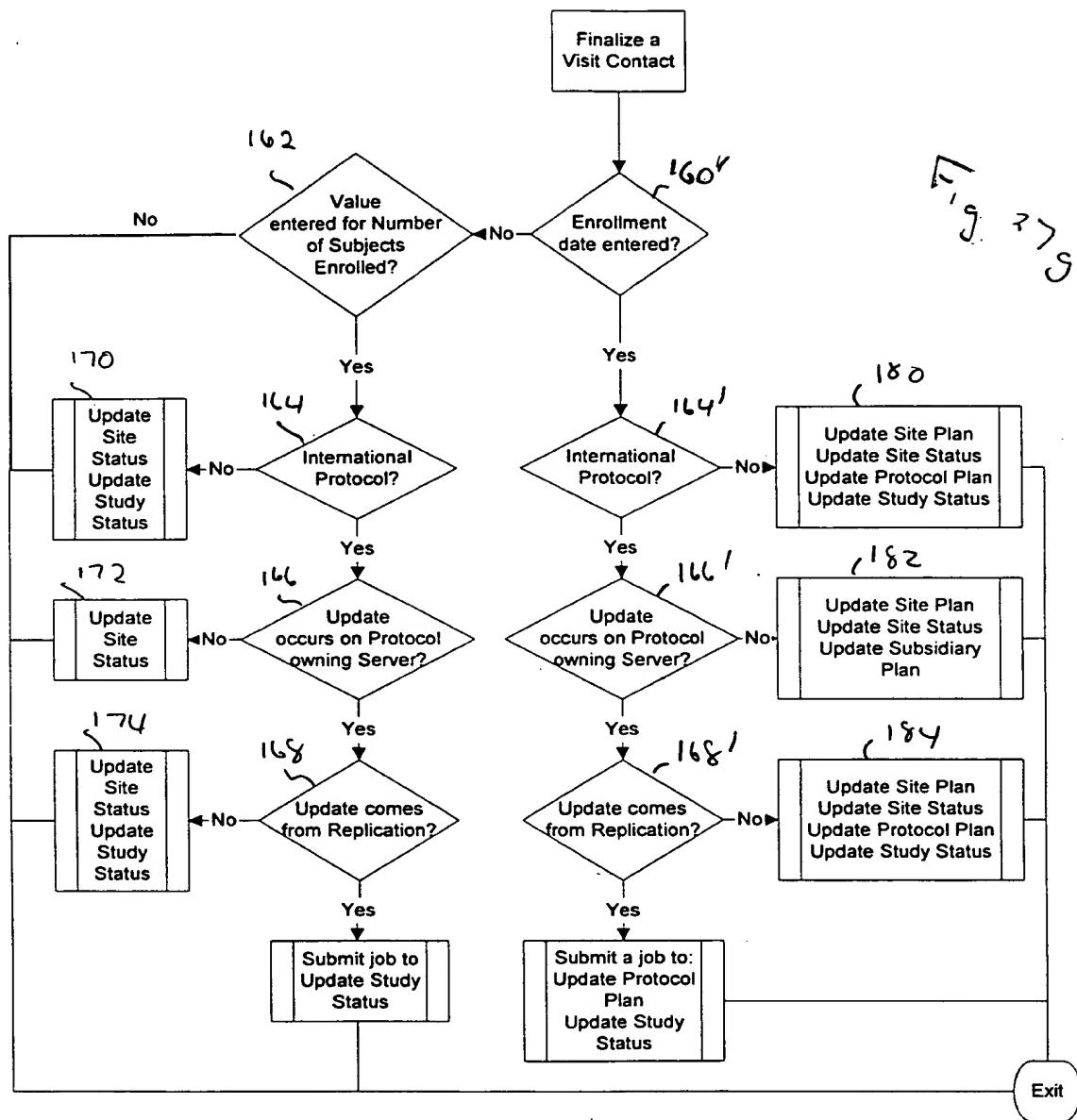
PROSIT driven for:  
 • Screening Ongoing/First Subject, First Visit



**Module: Event Manager**

PROSIT driven for:

- Enrollment Ongoing/First Subject Enrolled



Module: Event Manager

Milestone (site level) driven for:

- Enrollment Complete
- Clinically Complete
- Site Closed

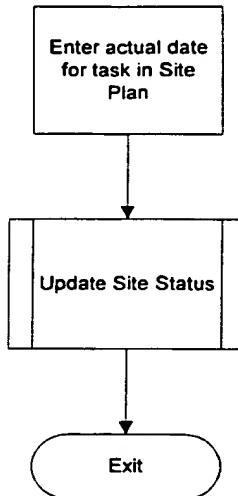
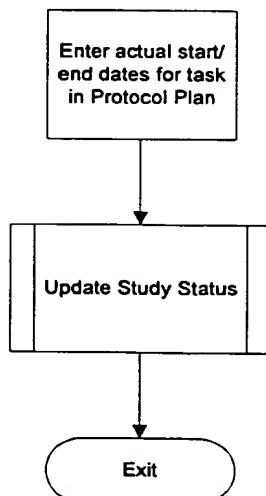


Fig. 27 h

Milestone (protocol level) driven for:

- Initiated/1<sup>st</sup> Site Initiated & Site Initiated
- Screening Ongoing/First Subject, First Visit
- Enrollment Ongoing/First Subject Enrolled
- Enrollment Complete
- Clinically Complete
- All Data In-House
- Data Cleanup Complete
- Database Locked
- CSR Approved



F.S. 27 i

PROSIT - Never Never Land

File Edit View Session Modules Window Help

Site Number Request

Request No	Submit date	Status	Site Country	Site Prefix	Protocol	Site ID	Requester	Investigator	Investigator
RQ - 10293	28-MAY-1998	ASSIGNED	Never Never Land	Q	P00036	1	Training, One	Investigator, One	Never Never Land
RQ - 10294	28-MAY-1998	ASSIGNED	Never Never Land	Q	P00036	2	Training, Two	Investigator, Two	Never Never Land
RQ - 10295	28-MAY-1998	ASSIGNED	Never Never Land	Q	P00036	3	Training, Three	Investigator, Three	Never Never Land
RQ - 10296	28-MAY-1998	ASSIGNED	Never Never Land	Q	P00036	4	Training, Four	Investigator, Four	Never Never Land
RQ - 10297	28-MAY-1998	ASSIGNED	Never Never Land	Q	P00036	5	Training, Five	Investigator, Five	Never Never Land
RQ - 10298	28-MAY-1998	ASSIGNED	Never Never Land	Q	P00036	6	Training, Six	Investigator, Six	Never Never Land
RQ - 10299	28-MAY-1998	ASSIGNED	Never Never Land	Q	P00036	7	Training, Seven	Investigator, Seven	Never Never Land
RQ - 10300	28-MAY-1998	ASSIGNED	Never Never Land	Q	P00036	8	Training, Eight	Investigator, Eight	Never Never Land
RQ - 10301	28-MAY-1998	ASSIGNED	Never Never Land	Q	P00036	9	Training, Nine	Investigator, Nine	Never Never Land
RQ - 10302	28-MAY-1998	ASSIGNED	Never Never Land	Q	P00036	10	Training, Ten	Investigator, Ten	Never Never Land
RQ - 10303	28-MAY-1998	ASSIGNED	Never Never Land	Q	P00036	11	Training, Eleven	Investigator, Eleven	Never Never Land
RQ - 10304	28-MAY-1998	ASSIGNED	Never Never Land	Q	P00036	12	Training, Twelve	Investigator, Twelve	Never Never Land
RQ - 10305	28-MAY-1998	ASSIGNED	Never Never Land	Q	P00036	13	Training, Thirteen	Investigator, Thirteen	Never Never Land
RQ - 10306	28-MAY-1998	ASSIGNED	Never Never Land	Q	P00036	14	Training, Fourteen	Investigator, Fourteen	Never Never Land
RQ - 11047	22-DEC-1998	RETURNED	Never Never Land	Q	P00041		Training, One	Hook, Captain	Never Never Land
RQ - 11048	22-DEC-1998	ASSIGNED	Never Never Land	Q	P00041	1	Training, One	Hook, Captain	Never Never Land
RQ - 11049	22-DEC-1998	ASSIGNED	Never Never Land	Q	P00041	2	Training, One	Bell, Tinker	Never Never Land
RQ - 11050	22-DEC-1998	RETURNED	Never Never Land	Q	P00041		Training, One	Investigator, Eight	Never Never Land
RQ - 11067	28-DEC-1998	RETURNED	Never Never Land	B	P00100		Training, One	Bell, Tinker	Never Never Land
RQ - 11068	28-DEC-1998	RETURNED	Never Never Land	A	P00102		Training, One	Bell, Tinker	Never Never Land
RQ - 11069	28-DEC-1998	RETURNED	Never Never Land	A	P00102		Training, One	Big Chief, Red	Never Never Land
RQ - 11070	28-DEC-1998	RETURNED	Never Never Land	A	P00102		Training, One	Bell, Tinker	Never Never Land
RQ - 11071	28-DEC-1998	ASSIGNED	Never Never Land	A	P00102	1	Training, One	Bell, Tinker	Never Never Land
RQ - 11072	28-DEC-1998	ASSIGNED	Never Never Land	A	P00102	2	Training, One	Big Chief, Red	Never Never Land

Ready

7/15/99 11:19:38

F  
19, 28

Fig. 29

PROSIT - Never Never Land - [Site Request Details [New]]

File Edit Actions Modules Window

Request No.: 14-F00102      Status: NEW

Protocol: 14-F00102

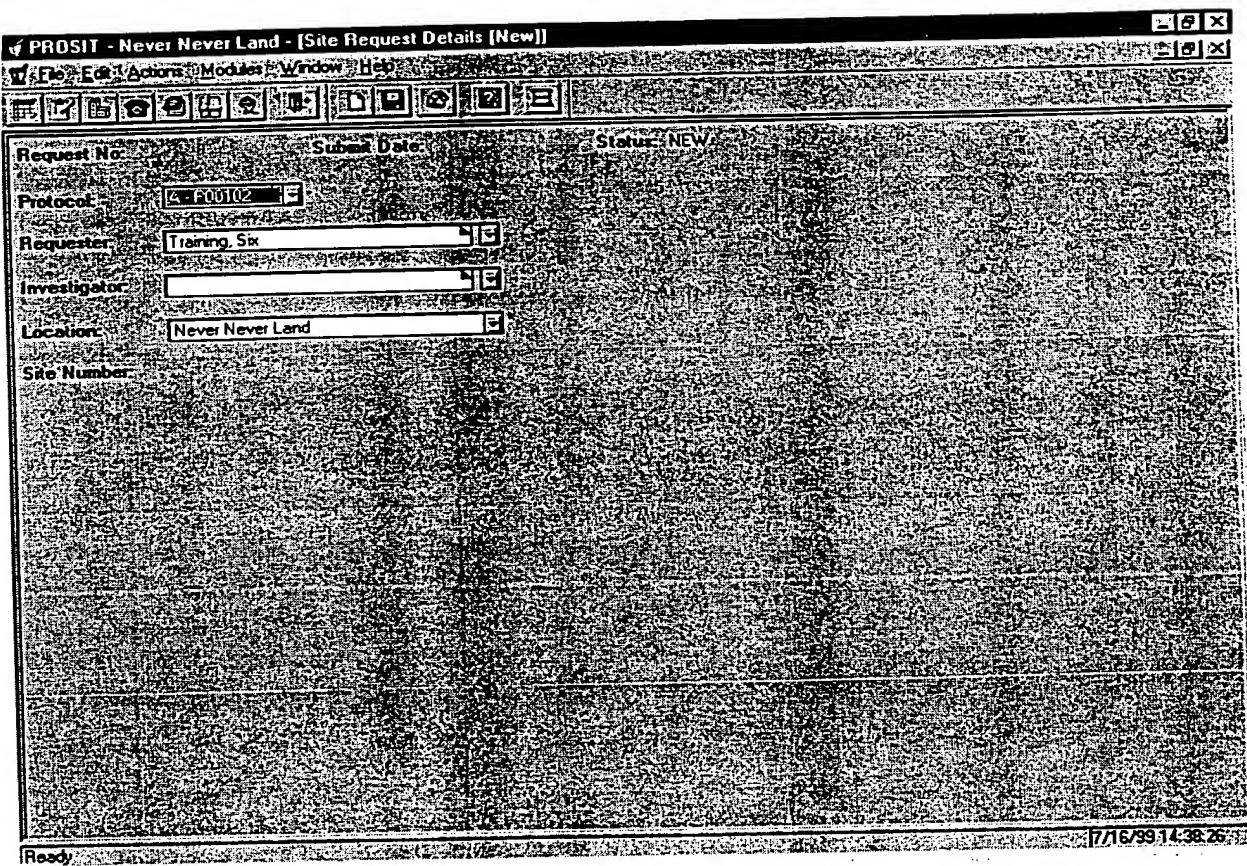
Requester: Training Six

Investigator:

Location: Never Never Land

Site Number:

Ready 7/16/99 14:38:26



09655617 096500

OCEGEGEY-O90500

PROSIT - UNITED STATES

File Edit View Actions Modules Forms Window Help

Site Administration Post Study Eval.

Protocol: I-P00324 Schering No: 000049  
Site No: [REDACTED] Investigator: Abduthey, G.

Schering Name: ANTERON  
Country: UNITED STATES

Protocol  
Study Status: PLANNED Notification: RESUME STUDY  
Notification Reason:  
Site Status: PLANNED Effective Amendment  
Data Collection Tool: CRF Effective Date: 04-NOV-1998  
Projected Enrollment  
Req. Minimum: 0 Site Enrollment: 0 Budget  
Prim. Location: YYYY Procedure Level: Site Level  
Pre-study Visit: [REDACTED] Currency: U.S. DOLLARS

Name	Function	Phone	Fax	Local Inv. No
Abduthey, G.	PRINCIPAL INVESTIGATOR			

Ready 105-Jan-1999

Fig. 30

PROSIT - UNITED STATES

File Edit View Actions Modules Forms Window Help

Site Administration Post Study Eval.

Protocol: I-P00324 Schering No: 000049 Schering Name: ANTERON  
Site No: Investigator: Abdulhey, G Country: UNITED STATES

Global Assessment: NOT RECOMMENDED Evaluated By: Rispoli, Marc C  
Evaluated On: 12-NOV-1998

ADEQUACY OF PATIENT SOURCE	GOOD	DRUG STORAGE AREA	ADEQUATE
FACILITIES	GOOD	LABORATORY	VERY GOOD
PRINCIPAL/CO-PRINCIPAL INVESTIGATOR	VERY GOOD	PFS TIME TO CONDUCT/SUPERV	VERY GOOD
STUDY STAFF	VERY GOOD	SUB INVESTIGATOR(S)	VERY GOOD

Ready 05-Jan-1999

Fig. 31

PROSIT - UNITED STATES

File Edit View Actions Modules Window Help

Schering Name: ANTERON

Protocol: I-P00324 Schering No: 00009  
 Site No:  Investigator: Abdutay, G. County: UNITED STATES

Locations | SP Personnel | Non SP Personnel | Non SP Personnel Locations

Active	Primary	Location	Role	Country	Address
<input checked="" type="checkbox"/>	<input type="checkbox"/>	HELSINKY YLIOPISTOLLINEN	(CO)SPONSOR	FINLAND	KESKUSAIPALA MEILAHDENTIE 2
<input checked="" type="checkbox"/>	<input type="checkbox"/>	3V45_HSC_MCMASTER_UNIV	CENTRAL IR	CANADA	This is address line 1 for external organization printing 12345571
<input checked="" type="checkbox"/>	<input type="checkbox"/>	410-2000 CREDIT VALLEY RD	CONTRACT	CANADA	MISSISSAUGA
<input checked="" type="checkbox"/>	<input type="checkbox"/>	SCCOR, INC.	CENTRAL IR	UNITED STATES	8211 SCCOR DRIVE
<input checked="" type="checkbox"/>	<input type="checkbox"/>	kanilworth	CENTRAL IR	UNITED STATES	address
<input checked="" type="checkbox"/>	<input type="checkbox"/>	YYYY	CENTRAL LA	CANADA	YYYY
<input checked="" type="checkbox"/>	<input type="checkbox"/>				

Ready 05-Jan-1999

F 5. 32

092228Z NOV 00

PROSIT - UNITED STATES

File Edit View Actions Modules Window Help

Site Personnel & Locations

Protocol: I-P00324 Schering No: 000049 Schering Name: ANTERON  
Site No: [REDACTED] Investigator: Abdutay, G Country: UNITED STATES

Locations SP Personnel Non SP Personnel Non SP Personnel Locations

Active	Write	Employee	Responsibility	Active Date	Inactive Date	Country	Expense	RESEARCH
<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	Ruspoli, Marc C	SITE REQUESTER	03-NOV-1998	00-0000	UNITED STATES	CHEM PR	
<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	Lee, J.S.	CLINICAL DATA COORDINATOR	12-NOV-1998	00-0000	UNITED STATES		
<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>			05-JAN-1999	00-0000			

Name of a site staff person from the Non SP Personnel tab: [REDACTED]

05-Jan-1999

Fig. 33

00605667 - 090600

PROSIT - UNITED STATES

File Edit View Actions Modules Window Help

Site Personnel & Locations

Protocol: I-P00324 Sourcing No: 000043 Schering Name: ANTERON

Site No: Investigator: Abdulhay, G Country: UNITED STATES

Locations SP Personnel Non SP Personnel Non SP Personnel Locations

Active Person	Responsibility	Active Date	Inactive Date	Country	Phone Number
Aepro, Mary S	PRINCIPAL INVESTIGATOR	03-NOV-1998	04-NOV-1998	UNITED STATES	908-603-3952
Aarons-You Ok, AL	DATA ENTRY CLERK/DATA COOR	04-NOV-1998	00-0000	US VIRGIN ISLANDS	vhgbbkcofd k
Abdulhay, G	PRINCIPAL INVESTIGATOR	04-NOV-1998	00-0000	UNITED STATES	23243-12341234-1
Aaronson, AL	DIETICIAN	12-NOV-1998	00-0000	UNITED STATES	
Aaronson, D	HOSPITAL ADMINISTRATOR	12-NOV-1998	00-0000	UNITED STATES	
6565656, 67777 76	CONTRACT/GRANTS ADMINISTRATOR	12-NOV-1998	00-0000	AMERICAN SAMOA	
Abbemont, T	IRB CHAIRMAN	12-NOV-1998	00-0000	UNITED STATES	1234
		05-JAN-1999	00-0000		

Name of a site staff person from the Non SP Personnel tab: 05-Jan-1999

Fig. 34

09655662 090500

**PROSIT - UNITED STATES**

File Edit View Actions Modules Window Help

Schering Name: ANTERON

Protocol: I-P00324 Schering No.: 000049  
 Site No: 1 Investigator: Abdushey, G Country: UNITED STATES

Locations: SP Personnel Non SP Personnel Non SP Personnel Locations

Associated Site Personnel: Aaronson, D

Primary Location	Role	Country	Address	City
<input checked="" type="checkbox"/> SCICOR, INC.	CENTRAL R&E/C	USA	8211 SCICOR DRIVE	IND
<input type="checkbox"/> YYYY	CENTRAL LABORATORY	CAN	YYYY	YY
<input type="checkbox"/> 410-2000 CREDIT VALLEY	CONTRACT RESEARCH ORGANIZATION	CAN	MISSISSAUGA,	ON
<input type="checkbox"/> 3V45 HSC MCMASTER	CENTRAL R&E/C	CAN	This is address line 1 for external organization printing 1234567, HAI	
<input checked="" type="checkbox"/> HELSINGIN YLLOPISTO	(CO)SPONSORING ORGANIZATION	FIN	KESKUSSAIRALA MELAHENTIE 2	002
keniworth	CENTRAL R&E/C	USA	address	city

A check indicates that this is the primary location for contacting this site staff person

05-Jan-1999

Figs. 35

0000000000000000

PROSIT - UNITED STATES

File Edit Actions Modules Forms Window Help

Site Study Tracking

Protocol: I-PO0324 Schering No: 00049 Schering Name: ANTERON

Country: UNITED STATES Site: [ ] Investigator: Abdullaev, G

Seq #	Task Name	Lastest Date	Actual Date
1	IPO0324-USA	-00-0000	02-NOV-1992
2	Completed Grant Request Form Received in Sub.	-00-0000	00-0000
3	CV of Laboratory Director(s) Received in S	-00-0000	00-0000
4	Budget Info Sheet (signed&dated by Inv) Rec	-00-0000	00-0000
5	CV of Laboratory Director(s) Received in Sub.	-00-0000	00-0000
6	CV of Laboratory Director(s) Sent to HO	-00-0000	00-0000
7	Completed Grant Request Form Sent to HO.	-00-0000	00-0000
8	Curriculum Vitae of Principal Inv.(s) Rec. in	-00-0000	00-0000
9	Curriculum Vitae of Principal Investigator(s)	-00-0000	00-0000
10	Curriculum Vitae of Sub-inv.(s) Received in S	-00-0000	00-0000
11	Curriculum Vitae of Subinvestigator(s) Sent t	-00-0000	00-0000
12	Doc. of Quality Control Proc. or Cert. Rec. in	-00-0000	00-0000
13	Doc. of Quality Control Proc. or Cert.Sent to	-00-0000	00-0000
14	FDA Form 1572 Received in Sub.	-00-0000	00-0000
15	FDA Form 1572 Sent to HO.	-00-0000	00-0000
16	Gov. Regulatory App. (w/ trans.) Sent to HO.	-00-0000	00-0000
17	Gov. Regulatory App. (w/trans.) Received in S	-00-0000	00-0000
18	Informed Consent Task(Trans)	-00-0000	00-0000
19	Informed Consent Doc. (with translation) Sent	-00-0000	00-0000
20	Site Closed	-00-0000	00-0000

The site whose tracking will be viewed/edited

05-Jan-1993

F 5. 36

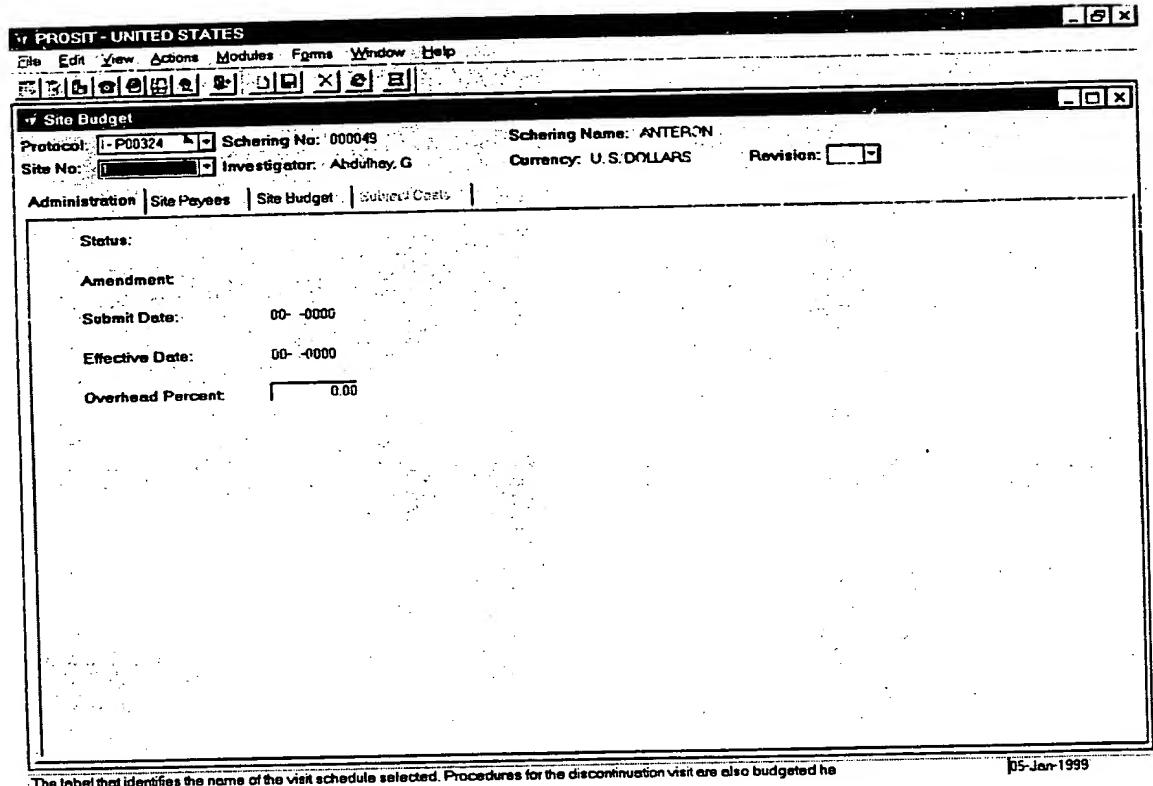
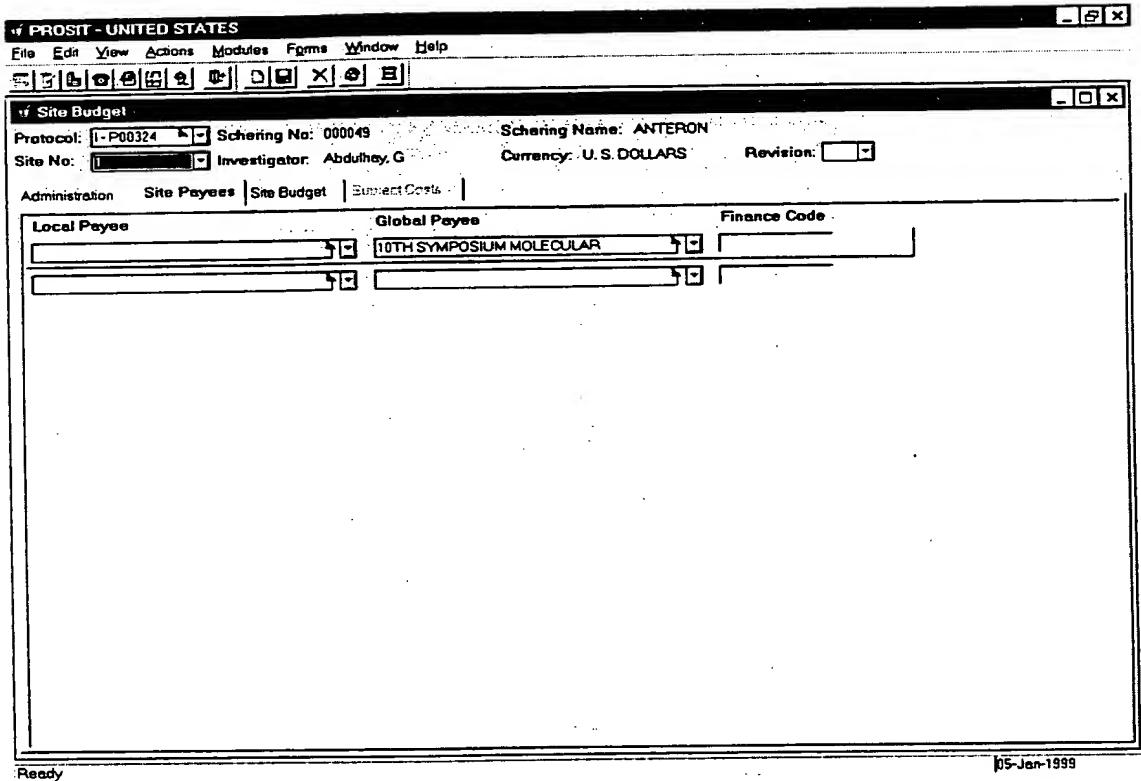


Fig. 37



Figs. 38

00000000000000000000000000000000

PROSIT - Never Never Land

File Edit View Actions Modules Forms Window Help

Site Budget

Protocol: A-P00102 Schering No: 000001 Schering Name: STEROIDS FOR SKIN TESTS  
 Site No: 4 Investigator: Big Chid. Red Currency: GOURDE Revision: 1

Administration Site Payees Site Budget Subject Costs

Protocol: P00102 Site No. 4		Revision: 1N REVISION Effective Date:		Amendment:	
Line Item	OH Default Payee	Unit Cost	Unit	Total	
<b>SUBJECT COSTS</b>					
<b>PROCEDURE COSTS</b>					
Laboratory Evaluation	Captain Hook	10.00	5	50.00	
Medical History	10TH SYMPOSIL	100.00	2	200.00	
		.00			
<b>ADDITIONAL VISIT COSTS</b>					
Evaluation	10TH SYMPOSIL	100.00	3	300.00	
		.00			
<b>ADJUSTMENTS</b>					
Recovery	Captain Hook	100.00	2	200.00	
		.00			
<b>OTHER COSTS</b>					
Advertisement	10TH SYMPOSIL	100.00	2	200.00	
Discovery	Captain Hook	20.00	3	60.00	
<b>TOTAL BUDGET</b>					
<b>PREVIOUSLY APPROVED</b>					
<b>REQUIRED</b>					

A description of the line item cost.

12-Aug-1999

Fig. 39

0000000000000000

PROSIT - UNITED STATES

File Edit View Actions Modules Forms Window Help

Site Budget

Protocol: I-P00324 Schering No: 000049 Schering Name: ANTERON  
 Site No: 1 Investigator: Abduray G Currency: U.S.DOLLARS Revision:

Administration | Site Payees | Site Budget **Subject Costs** | Treatment Schedule: Treatment Schedule 1

Line Item	Subjects Budgeted >	Visit # >		
		1	2	3
13C-UREA BREATH TEST		\$0.00	\$0.00	\$0.00
12-LEAD ECG		\$0.00	\$0.00	\$0.00
2-VIEW XRAY		\$0.00	\$0.00	\$0.00
24-HOUR URINE COLLECTION		\$0.00	\$0.00	\$0.00
4-VIEW XRAY		\$0.00	\$0.00	\$0.00

Ready 05-Jan-1999

Fig. 40

PROSIT - UNITED STATES

File Edit Actions Modules Forms Window Help

Pre-Study Visit

Protocol: I-P00324 Schema No.: 000049 Schema Name: ANTERON  
Pre-Study Visit No.: 10566 Principal Investigator: Aasebo, U Country: NORWAY

Pre-Study Visit SP Personnel NSP Personnel Discussion Items Evaluation

Potential Investigator: Aasebo, U Potential Study Location: Location Name  
Country: AFGHANISTAN

Visit Date: 18-NOV-1998 Time: 16:25 Finalized: DD-0000

Schering Participants: Rispoll, Marc C

Investigator Site Participants: Non-Registered() Aasebo, U

Ready 05-Jan-1999

F5. 41

PROSIT - UNITED STATES

File Edit Actions Modules Forms Window Help

Pre-Study Visit

Protocol: I-P00324 Schering No: 000049 Schering Name: ANTERON

Pre-Study Visit No: 10566 Principal Investigator: Aslebo U County: NORWAY

Pre-Study Visit SP Personnel NSP Personnel Discussion Items Evaluation

Registered Site Personnel - Title

Aslebo U

Nos - Registered Site Personnel  
Last Name First Name Title

This is a registered site person

DS-Jan-1999

Figs. 42

09655557 090600

PROSIT - UNITED STATES

File Edit Actions Modules Forms Window Help

Pre-Study Visit

Protocol: I-P00324 Schering No: 000049 Schering Name: ANTERON

Pre-Study Visit No: 10566 Principal Investigator: Aasebo, U Country: NORWAY

Pre-Study Visit SP Personnel NSP Personnel Discussion Items Evaluation

**STUDY CONSIDERATIONS**

- Pre Clinical Data
- Clinical Data
- Investigator Brochure
- Protocol
- Case Report Forms
- Monitoring Responsibilities
- Study Schedule
- Principal Investigator Responsibilities
- Sub-Investigator Responsibilities
- Staff Responsibilities
- Grant
- Payment Schedule

**ETHICAL CONSIDERATIONS**

- Curriculum Vitae
- Principal Investigator
- Co-Principal Investigator
- Sub-Investigator
- Lab Director
- Laboratory Certification
- Laboratory Q.C. Procedures
- Laboratory Performance Ranges
- DEA Regulators and Drug Control
- Adequacy and Accuracy of Records
- Availability of Patient Records
- Drug Accountability and Disposition
- IRB/EC
- Approval Documents
- Responsibilities
- Retention of Records
- Informed Consent
- FDA 1572 OR
- Investigator Agreement
- Nature of FDA Inspection

Ready 05-Jan-1999

Figs. 43

PROSIT - UNITED STATES

File • Edit • Actions • Modules • Forms • Window • Help

Pre-Study Visit

Protocol: I-P00324 Schering No.: 000049 Schering Name: ANTERON  
Pre-Study Visit No.: 10566 Principal Investigator: Aasbo, U Country: NORWAY

Pre-Study Visit | SP Personnel | NSP Personnel | Discussion Items | Evaluation |

Global Assessment: RECOMMENDED

ADEQUACY OF PATIENT SOURCE: GOOD  DRUG STORAGE AREA:   
FACILITIES:  LABORATORY:   
PRINCIPAL INVESTIGATOR/CO-PRINCIPAL INVESTIGATOR:  PTS TIME TO CONDUCT/SUPERVISE: VERY GOOD   
STUDY STAFF:  SUB INVESTIGATORS:

Ready 05-Jan-1999

Fig. 44

PROSIT - UNITED STATES

File Edit Tools Actions Modules Forms Window Help

Visit Contact

Protocol: I-P00324 Schering No: 000049 Schering Name: ANTERON

Site No: [redacted] Contact: 00011266 - 04-Nov-1998 uninitialised

Contact Information

Originator: Rispoll, Marc C Reason: CLINICAL STUDY SUPPLIES

Date: 04-NOV-1998 Time: 00:00

Meeting Location

Site Roster: Testing the new prosit 1.03.1 build  
 Other:

The investigator site is:

Recommended  
 Not Recommended

Schering Participants

Rispoll, Marc C

Non-Schering Participants

Aspro, Mary S

The study center that was involved in this contact

05-Jan-1999

Fig. 45

PROSIT - Never Never Land

File Edit Tools Actions Modules Forms Window Help

Electronic Mail Contact

Schering Name: MOMETASONE

Protocol: P00036 Schering No: 032088  
Site No: 4 Contact: 00008480 - 02-Aug-1999 finalized

Contact Information

Originator: Dating, John Reason: ADVERSE EVENT  
Date: 02-AUG-1999 Time: 05:01

Phone Contact Details

Outside Party Phone #: 555-555-5555

Schering Participants

But, Thud

Non-Schering Participants

[03-Aug-1999]

Ready

F15, 46

PROSIT - UNITED STATES

File Edit Tools Actions Modules Forms Window Help

Visit Contact

Protocol: I-P00324 Schering No: 000049 Schering Name: ANTERON  
 Site No:  Contact: 00011286 - 04-Nov-1998 unfinished

Visit Contact Discussion Items

New Pre-Clinical or Clinical Data	Personnel Responsibilities	Clinical Supplies
<input type="checkbox"/> Efficacy	<input type="checkbox"/> Principal Investigator	<input type="checkbox"/> Quantity
<input type="checkbox"/> Adverse Events	<input type="checkbox"/> Sub-Investigator	<input type="checkbox"/> Storage
<b>Protocol Adherence</b>		
<input type="checkbox"/> Subject Selection	<input type="checkbox"/> Staff	<input type="checkbox"/> Dispensing
<input type="checkbox"/> Conduct Of Study	<input type="checkbox"/> Location Of Patient Info.	<input type="checkbox"/> Packaging/Labeling/Coding
<input type="checkbox"/> Adverse Events	<input type="checkbox"/> Clinical Laboratory	<input type="checkbox"/> Randomization
<input type="checkbox"/> Concomitant Medications	<input type="checkbox"/> Equipment	<input type="checkbox"/> Recertification Date
<b>Case Report Form (CRF) Records</b>		
<input type="checkbox"/> CRF Completion vs. Patient Enrollment	<input type="checkbox"/> Other	<input type="checkbox"/> Drug Disclosure Envelopes
<input type="checkbox"/> CRF Completeness		<input type="checkbox"/> Documentation of Accountability
<input type="checkbox"/> CRF Availability, Storage and Retention		

Monitoring Activities

- Action Taken By PI and Monitor to correct deficiency
- Source Document Verification Completed
- Consents Reviewed
- Source Document Checked

\* Required to finalize the site contact.

The study center that was involved in this contact:

05-Jan-1999

1-15.47

PROSIT - UNITED STATES

File Tools Actions Modules Window Help

Site Tracking

Protocol: I-P00324 Schering No: 000049 Schering Name: ANTERON

Site: 1 Contact: 11286 Visit Unfinalized As of: 04-Nov-1988

Enrollment Tracking | Ineligible For Screening

	Enrollment as of Unfinalized Site Visit	Enrollment as of Latest Finalized Visit
Potential Subjects Ineligible for Screening:	2	0
Number of Subjects Screened:	10	0
Number of Subjects Failed Screening:	2	0
Number of Subjects Enrolled:	8	0
Number of Subjects Discontinued total:	2	0
Adverse Events:	1	0
Other:	1	0
Number of Subjects Complete:	5	0
Number of Subjects Ongoing:	1	0

Ready 05-Jan-1989

Figs. 48a

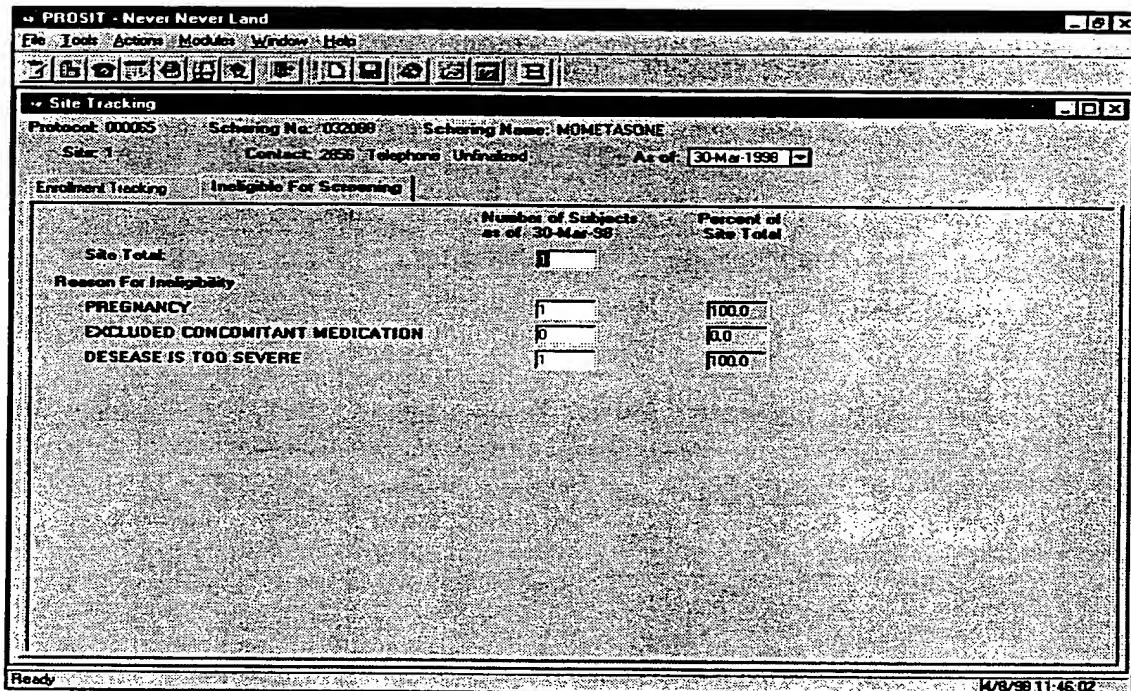


Fig. 4E-6

PROSIT - UNITED STATES

File Edit View Actions Modules Window Help

Subject Visit Tracking

Protocol: I-P00324 Site: 1 Contact: 11286

Screening Number: 1 Subject Number: 1 Initials:

Subject Visit Summary | Discont. | Unsched. | 2 | 1 |

Gender: MALE	Date of Birth: 01-JAN-1971	Age at Enrollment: 27 Years
Signed Consent: 02-NOV-1998	Last Visit Number: 0	Discontinuation Visit:
Enrollment: 03-NOV-1998	Current Phase: MAINTENANCE	Complete: <input checked="" type="checkbox"/>
Therapy Started: 00-0000	Reason For Discontinuation:	Usable/Evaluable: <input checked="" type="checkbox"/>
Therapy Ended: 00-0000	Discontinuation Date:	00-NOV-1998
Days On Therapy:		
Additional Subject Data:		
SUBJECT 1:		

Ready 05-Jan-1999

Fig. 49

PROSIT - UNITED STATES

File Edit View Actions Modules Window Help

Subject Visit Tracking

Protocol: I-P00324 Site: Contact: 11285

Screening Number: Subject Number: Initials:

Subject: Visit Summary Discon. Unsched. 2 | 1

Visit No	Amendment	Visit Label	Visit Date	Delta	To Do	CRF Status	SDV Status
1		Visit 1	09-Nov-1998		<input type="checkbox"/>	COLLECTED	<100%
2		Visit 2	16-Nov-1998	6	<input type="checkbox"/>	PARTIALLY COLLECTED	<100%
3		Unscheduled Visit	23-Nov-1998		<input checked="" type="checkbox"/>	PARTIALLY COLLECTED	<100%
4		Discontinuation Visit	30-Nov-1998		<input checked="" type="checkbox"/>	NOT COLLECTED	<100%

Ready 05-Jan-1999

Fig. 50

0965667 - 090600

00090602-090600

PROSIT - UNITED STATES

File Edit View Actions Modules Forms Window Help

Formulated Materials Requisition

FMR Req. ID: 184

Administration Materials

**Protocol Information**

Protocol Number: A-P10240 Schering No: 000028 A AND D  
Program Code: F05 Marketed  
Expense Center: 1495-WORLDWIDE RSCH OA  
Requisition Source: ANIMAL HEALTH DOMESTIC/INTERNATIONAL  
Requested by: Desontos, Marc  
Authorized by: Desontos, Marc  
Date Required For Packaging: 22-DEC-1998 Blinding Required:   
Special Directions and Blinding (explain blinding requirements if any):

A protocol under which the requested supplies will be utilized

05-Jan-1999

Fig. 51

09055627 090600

PROSIT - UNITED STATES

File Edit View Actions Modules Forms Window Help

PSR Request Protocol Packaging

Protocol: I-P00324 Schering No:000049 Schering Name: ANTERON  
Country: UNITED STATES PSR No: 1409

PSR Information | Components | Ship To |

Project Accounting Code: F01 - 000049 - 303E Exp Center: 1477 RESEARCH SYS

New Protocol/Site:  Study Type:  Blind  Open

Study Monitor: Print PC

Random Code Format: CODE ENVELOPES

Requested by: Ruspoli, Marc C

Authorized by: 3,3

Required Ship Date: 31-MAR-1999 Random Code Generation ID: Select Site

IND Labeling Date: 00-0000

Special Instructions:

Attachments: PROTOCOL   
LABEL FORMAT   
LABELING INSTRUCTIONS   
DEA FORM 222C   
CONFIRMATION DEA REG. N

A number generated when the PSR is first saved to uniquely identify the PSR. This is not the PSR number generated by the clinic.

05-Jan-1999

Fig. 52

PROSIT - UNITED STATES

File Edit View Actions Modules Forms Window Help

PSR Request: Protocol Packaging

Protocol: C-C98005 Schering No: 032088 Schering Name: MOMETASONE  
Country: UNITED STATES PSR No: 1000

PSR Information Components Ship To

Schering No.	Schering Name	Test Dose Form	Strength/ concentration	Package Description/Fill	Required Units
032088	MOMETASONE	ORAL AERPR	UNKNOWN		

The Schering number of the drug that will be packaged. 10/24/1999

Fig. 53

09665662 - 090600

PROSIT - UNITED STATES

File Edit View Actions Modules Forms Window Help

PSR Request: Protocol Packaging

Protocol: I-P00324 Schering No:000049 Schering Name: ANTERON  
Country: UNITED STATES PSR No: 1489

PSR Information Components Ship To

Location: SCHERING CANADA INC  
Address: 170 ONEIDA STREET  
City: POINTE CLAIRE US State/Other:  
Postal Code: HSR 1B4 Country: CANADA  
Phone: Fax: 514 426 7300  
Attention:

The subsidiary to which the clinical supplies will be shipped.

05-Jan-1999

Fig. 54

PROSIT - UNITED STATES

File Edit View Actions Modules Forms Window Help

Material Transfer Request

Protocol: C-P98615 Schering No: 034117 Schering Name: DESLORATADINE

Country: UNITED STATES Site No: 1 MTR No:

MTR Details Ship To:

Inventory Location: Requested Ship Date: 00-0000

Requested By: Caprio, Denise M

Authorized By:

Expense Center: 1751 SR DIR INTL CLN RES Intended Use Of Material

Material Type Batch No. PSR No. FMR No. Quantity Quantity On Hand

The type of material to be shipped.

14-Aug-1999

FIS, 55

RT

000000000000000000000000

PROSIT - UNITED STATES

File Edit View Actions Modules Forms Window Help

Material Transfer Request

Protocol: C-P98615 Schering No: 034117 Schering Name: DESLORATADINE

Country: UNITED STATES Site No: 1 MTR No: AAD00637

MTR Details: Ship To:

Location:   
Address:   
City:  State/Province:   
Postal Code:  Country:   
Phone:  Fax:   
Attention:

Shipping/Packaging Instructions:

The name of the person who will receive the shipment at this location.

Fig. 56

09656672 09656600

PROSIT - UNITED STATES

File Edit Actions Modules Forms Window Help

Random Code Request - New

Protocol: Q-P00759 Schering No: 032088 Schering Name: MOMETASONE  
Random Code Req ID: Date Prepared: 00-0000 Pctl Finalization Dt: 21-JUL-1999

To: [ ] Copies: [ ]  
From: Caprio, Denise M  
Random Code Type: [ ]  
Generate Random Code by: [00-0000]  
Number of United States Sites: 2 First United States Site ID:  
Number of International Sites: First International Site ID:  
Subj: Randomized by: [ ] Treatment Arm: [ ] Subjects: [ ]  
Subj: Replaced by: [ ]  
Subj nbr assigned by: [ ] Total Subjects: 0  
Number of Stratification:

A number generated when the RCR is first saved to identify the random code request memo.

11/18/99

Fig. 57

PROSIT - UNITED STATES

File Actions Modules Window Help

Check Control

Userid: RENOWSKIG Renowski, George

Check Out

Date: 13-Jul-1999 Extra Items Status: Checked out data available

Protocol	Site	Primary Location	Site Investigator	Site Requester
B93214		No Site - Pcl only		
B94055		No Site - Pcl only		
B94056		No Site - Pcl only		

Request Date Status Check In Date Checked In Date Reply from server

The logon ID of the user whose status is being requested 12-Aug-1999

Fig. 58

## SUBJECT DETAIL REPORT

T.S. 59

PROSIT - SUBJECT DETAIL REPORT																												
Schering No.	032088 MOMETASONE	Working Study Title	Protocol No. - Site No.																									
Principal Investigator	Daniel W AARONSON, M.D.	Study Location	H000017- Monitor																									
<b>SUBJECT: 6001AKM/1</b> Gender: M      Last Visit Date: 09-APR-1998 Age: 30 years      Last Visit Label: Visit 3 Date of Birth: 07-AUG-1967 Signed Consent: Evaluable: Reason for Discontinuation																												
As Of: 05-Mar-1998      Contact ID : 6038 <table border="1"> <thead> <tr> <th>Visit</th> <th>Date (Delta)</th> <th>SDV</th> <th>CRF Status</th> <th>Pages Collected</th> </tr> </thead> <tbody> <tr> <td>Screening</td> <td>05-MAR-1998 (0)</td> <td>100%</td> <td>COLLECTED</td> <td></td> </tr> <tr> <td>Visit 1</td> <td>12-MAR-1998 (5)</td> <td></td> <td>COLLECTED</td> <td></td> </tr> <tr> <td>Visit 2</td> <td>26-MAR-1998 (12)</td> <td>100%</td> <td>COLLECTED</td> <td></td> </tr> <tr> <td>Visit 3</td> <td>09-APR-1998 (12)</td> <td>100%</td> <td>COLLECTED</td> <td></td> </tr> </tbody> </table>				Visit	Date (Delta)	SDV	CRF Status	Pages Collected	Screening	05-MAR-1998 (0)	100%	COLLECTED		Visit 1	12-MAR-1998 (5)		COLLECTED		Visit 2	26-MAR-1998 (12)	100%	COLLECTED		Visit 3	09-APR-1998 (12)	100%	COLLECTED	
Visit	Date (Delta)	SDV	CRF Status	Pages Collected																								
Screening	05-MAR-1998 (0)	100%	COLLECTED																									
Visit 1	12-MAR-1998 (5)		COLLECTED																									
Visit 2	26-MAR-1998 (12)	100%	COLLECTED																									
Visit 3	09-APR-1998 (12)	100%	COLLECTED																									
<b>SUBJECT: 6002KG/2</b> Gender: F      Last Visit Date: 09-APR-1998 Age:      Last Visit Label: Date of Birth: 28-JUL-1969 Reason for Discontinuation DEATH																												

Ready

5/5/98 13:27:45

## QUERYING

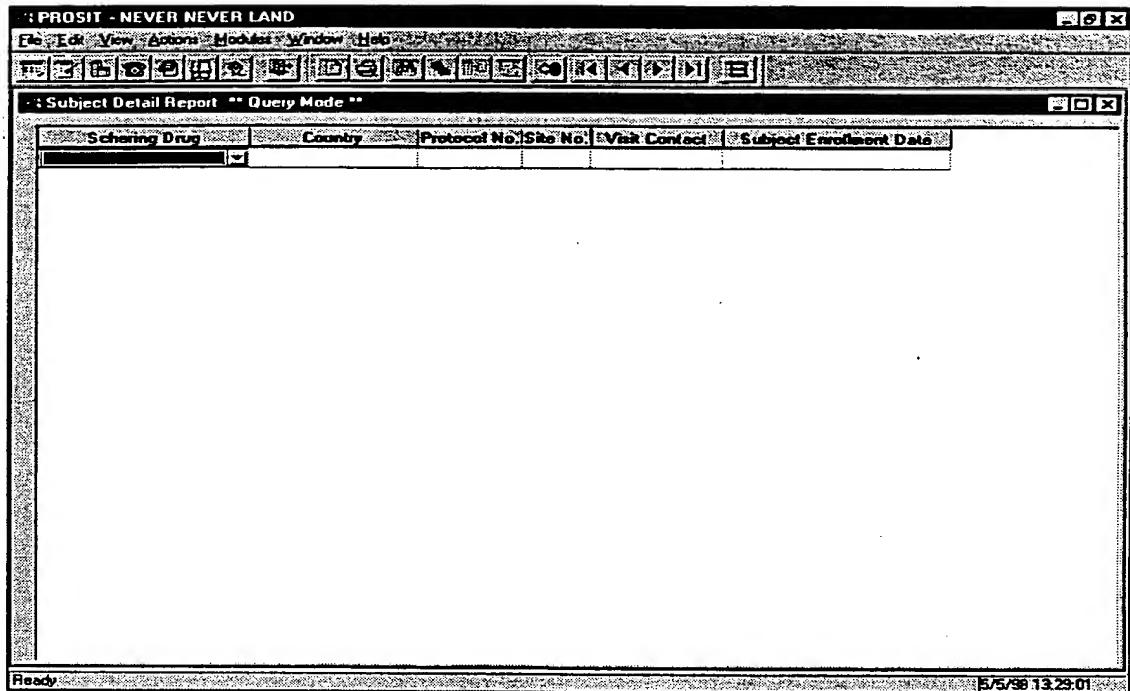


Fig. 60

09555652 - 0906000

## SUBJECT SUMMARY REPORT

PROSIT - NEVER NEVER LAND

File Edit View Actions Modules Window Help

Site / Subject Summary Report

PROSIT - SITE / SUBJECT SUMMARY REPORT

Schering No.	032068 MOMETASONE	Working Study Title Mometasone vs. Budesonide in Asthma	Protocol No. - Site No.	000003-1
Principal Investigator	J G ORTIZ	Study Location ENGELWOOD, CO, UNITED STATES	Monitor	

Site 1 Details

Site Status: ENROLLMENT ONGOING      # Subjects Projected:      Data Collection Tool : CRF

Enrollment Summary	Site Level	Subj. Level <sup>1</sup>	Milestones	Monitoring Summary
# Subj. Ineligible for Screening:	0		Site Initiation Visit Date:	Total Visits Completed : 6
# Subj. Screened:	0	2	First Subject Screened:	Visits Monitored : 4 (66%)
# Subj. Failed Screening:	0	0	First Subject Enrolled:	Visits 100% SDV : 1 (16%)
# Subj. Enrolled (% Projected)	0	2	Last Subj. Enrolled to Date:	Visits Collected : 4 (66%)
# Subj. Ongoing:	0	1	Enrollment Complete:	Date of Last Contact: 25-MAR-1998
# Subj. Discontinued:	0	0	Last Subject Last Visit:	Date of Last Visit: 25-MAR-1998
# Subj. Complete:	0	1	Close out Visit:	Visits at the Site: 1

Per Subject Summary<sup>2</sup>

Subject ID	Age	Gender	Date Enrolled	Status	Last Visit (phase)	Last Visit Date	Reason for Discontinuation	Eval	Date RX Started	Date RX Stopped
0001 DL 1	25YRS.	M		O	IVI1	04-FEB-1998		UN		
					SCR					

7:00 AM 7 F 0 11:11 12:08 PM

Start Microsoft Word - REPORT1 PROSIT - NEVER NE...

1/31/61

09553667 095600

# MONITORING STATUS REPORT

F15. 62

PROSIT - MONITORING STATUS REPORT																																																																																																																	
Enrollment No.: 00000 MONITASONE			Working Title: Monitoring vs. Butazone in Arthritis			Protocol No./Site No.: 000000-1																																																																																																											
Principal Investigator: J GORTIZ			Study Location: ENGLEWOOD CO-UNITED STATES			Monitor:																																																																																																											
<b>Site 1 Summary</b> <table border="1"> <thead> <tr> <th colspan="3">Status</th> <th colspan="3">Visits</th> <th colspan="6">Subjects</th> </tr> </thead> <tbody> <tr> <td>Present:</td> <td colspan="2">AMENDED</td> <td>Completed:</td> <td colspan="2">0</td> <td>Projected:</td> <td colspan="6"></td> </tr> <tr> <td>Site:</td> <td colspan="2">ENROLLMENT ONGOING</td> <td>Non-compliant:</td> <td colspan="2">0 (0%)</td> <td>Actual # Enrolled:</td> <td colspan="6">2</td> </tr> <tr> <td>Visits at the site:</td> <td colspan="2">4</td> <td>100% SDV:</td> <td colspan="2">1 (100%)</td> <td>Actual # Enrolled:</td> <td colspan="6">1</td> </tr> <tr> <td>Date of last visit:</td> <td colspan="2">28-Mar-1998</td> <td>Calibrated:</td> <td colspan="2">0 (0%)</td> <td>Actual # Completed:</td> <td colspan="6">1</td> </tr> </tbody> </table>												Status			Visits			Subjects						Present:	AMENDED		Completed:	0		Projected:							Site:	ENROLLMENT ONGOING		Non-compliant:	0 (0%)		Actual # Enrolled:	2						Visits at the site:	4		100% SDV:	1 (100%)		Actual # Enrolled:	1						Date of last visit:	28-Mar-1998		Calibrated:	0 (0%)		Actual # Completed:	1																																											
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Subject	V1	V2	V3	V4	V5	V6	V7	V8	V9	V10	V11	V12	V13	V14	V15	D/C Reasons																																																																																																	
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TIC GUARD	C				C																																																																																																												
Completed	2	1	1	1	0	0	1	0	0	0	0	0	0	0	0																																																																																																		
Non-compliant	1	1	1	1	0	0	0	0	0	0	0	0	0	0	0																																																																																																		
Cancelled	1																																																																																																																
Legend: C = Completed; 100% SDV; GU = Key Unusually; (+100) = 100% SDV; (+) = Calibrated/adjusted = Discontinued V1 = site enrollment; V2 = baseline; V3 = (v1); V4 = (n2); V5 = (Gu1); V6 = (Gu2); V7 = screen V2																																																																																																																	

09655657 - 0906000

5/5/98 14:36:01

## SITE PERSONNEL AND LOCATION REPORT

PROSIT - Never Never Land

File ECR View Actions Modules Window Help

Site Personnel & Locations Information Report

**PROSIT - SITE PERSONNEL & LOCATIONS INFORMATION SHEET**

Schering No.	032088 MOMETASONE	Working Title	Mom vs Dad in Asthma
Protocol No.	AP00045-1	Expense Center	1763 - CLINICAL RESEARCH - ALLERGY II
Principal Investigator	J TABASCOMINGUILLAN	Monitoring Country	Never Never Land

**NON SP PERSONNEL**

Maid, Mer	Tabascominguillan, J	Bell, Tinker
IRB CHAIRMAN	PRINCIPAL INVESTIGATOR	STUDY COORDINATOR
NNL	NNL	NNL
Active: 22-Apr-1998	Active: 22-Apr-1998	Active: 22-Apr-1998

**CENTRAL IRB/EC**

MERMAID ROCK
2 Stone Skip
NNL

**TREATMENT CENTER**

PIRATE SHIP
Out at Sea

Next: 6/19/98 14:07:04

FIS. 63

## CONTACT INFORMATION REPORT

PROSIT - UNITED STATES

File Edit View Actions Modules Window Help

Contact Information Report

PROSIT - CONTACT INFORMATION SHEET

Schering No.	000058 NIACIN	Working Title	domestic
Protocol No.	A000001		

PROTOCOL A000001 EXTERNAL ORGANIZATIONS

CENTRE UNIVERSITAIRE DE SANTE	61200	National Genetics Institute
Gunn, Mark C	Aarons, A.L	Kedmon, D
DE L'ESTRE 3001 12E AVENUE	1200 Fleet street	5623 Green Valley Circle # 104
Voice: 37		FAX: 1-310-936-6610
FAX: Quebec NORD	Voice: FAxCAN	FAX: 1-310-936-6610
SHERBROOKE,QUE	manchester, London UK	Culver City USA

SITE 1 SP PERSONNEL

Grau, P.C	Ripoll, Marc C
DSS SPECIALIST	PROJECT PHYSICIAN
IL-10 IN IBD/HIV	KEY PRODUCT MGMT.
USA	USA
Active: 20-Feb-1998	www.zester.com
	Active: 20-Feb-1998

Dunn, Mark C  
SITE REQUESTER  
WORLDWIDE RCH QA  
USA

Ready 2/26/98 9:52:37

FIS, 64

09655657 096600

## FORMS

PROSIT - Never Never Land

File Edit Actions Modules Forms Window Help

Pre-Study Visit

Protocol: 000065  
Pre-Study Visit No.: 2057  
Pre-Study Visit: SP-Pocca  
Potential Investigator: Hook, Cap  
Country: Never Never Land  
Visit Date: 31-MAR-1998 Time: 11:00 Finalized: 00-0000

Sickening Participants:  
Pan, Peter J.  
Butt, Thud

Pre Study Investigator Visit

Medication: MOMETASONE  
Country: Never Never Land  
Evaluation: RATE SHIP

Investigator Site Participants: Non - Registered (\*)  
Deck, Hanz  
Hook, Captain  
Smeee, Mister

Ready 4/1/99 17:18:17

Fig.  
65